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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee Report And Report of the Work Group on E-Pedigree

Stan Goldenberg, RPh, Chair and Board Member
Bill Powers, Board President
Ruth Conroy, PharmD, Board Member
D. Timothy Dazé, Esq., Board Member
Robert Swart, PharmD, Board Member

On December 5, 2007, the Enforcement Committee held a Work Group on E-Pedigree Meeting in Sacramento. There was no time to hold an Enforcement Committee Meeting in conjunction with the Work Group Meeting because of the number of speakers requesting time to present information and the e-pedigree topics scheduled for discussion. Consequently the Enforcement Committee will meet at the end of the Board Meeting on January 23, 2008, to hear enforcement items not related to e-pedigree.

A summary of the Workgroup on E-Pedigree Meeting held December 5, 2007 is provided in **Attachment 1**.

A: Report of the Work Group on E-Pedigree:

1. Report of the Work Group on E-Pedigree Meeting Held December 5, 2007

The December 5, 2007 meeting of the E-Pedigree Work Group was a very large meeting (approximately 400 people attended) held in Sacramento. Minutes of the meeting, and the PowerPoint presentations made during the meeting, are provided at the end of this tab section.

Presentations were made by drug manufacturers, software companies, associations, pharmacies and individuals. Presentations were made by:

- Board of Pharmacy – on a review of where the costs for a prescription drug go
- EPCglobal – on the standards implementation progress
- Alien Technology – on the status of RFID Gen 2 UHF tags
- CPhA – on the readiness of California community pharmacies to implement e-pedigree requirements
- NCPA— on the readiness of California community pharmacies to implement e-pedigree requirements

- GPhA – on the issues generic manufacturers have in meeting California's requirements
- Three Rivers – on this generic manufacturer's efforts to comply with California's requirements
- Teva – on this generic manufacturer's efforts to comply with California's requirements
- Watson – on this generic manufacturer's efforts to comply with California's requirements
- PhRMA – on the readiness and interest of pharmaceutical companies to meet California's requirements
- CHI – on the concerns of the biotechnology companies in meeting California's requirements
- HDMA – on the efforts of the wholesale distributors to be ready for California's requirements
- Aegate – on an alternative method to authenticate medicine at the point of dispensing
- NCPD – on concerns of smaller, secondary wholesalers in meeting California's requirements
- Stephanie Aleong – on her experience as a federal prosecutor in Florida involving counterfeit drugs in the supply chain
- Siemens – on the readiness of the industry to implement electronic pedigrees
- DDN Pharmaceutical Logistics – on its readiness to implement California's requirements
- Safeway – on issues it faces in meeting California's requirements
- Longs – on issues it faces in meeting California's requirements
- Kaiser Permanente – on issues it faces in meeting California's requirements

Much of the discussion was similar to that provided at prior Work Group Meetings, and centered on the difficulties some supply chain members state they will have in meeting the January 1, 2009 deadline. There were repeated requests for the board to delay implementation of the requirements until January 1, 2011.

Each speaker made comments supporting the need for added safeguards to the nation's drug supply, although the route to secure these safeguards differed. Each speaker stated that the first concern is for patient safety and consumer protection.

The greatest number of speakers identified obstacles to a 1/1/09 implementation date. The following barriers to timely implementation were among those identified by these speakers: an asserted lack of a single tagging standard and confusion about what type of item tagging should be used – meaning that those entities downstream (i.e., pharmacies and wholesalers) will have to be able to read any tag, increasing their costs and complexity to implement; an asserted lack of maturity in the technology supporting electronic pedigrees and the complexity of integrating software to receive and transmit pedigree data from the reading of a tag; high implementation costs that could not be recouped; concerns about the possible damage to some medicines exposed to RFID tags/readers; and a general complaint about the lack of sufficient time to implement this

requirement by 2009, 2011 or even 2013. While some provided comments in support of California's requirements for serialization to the saleable package level, some expressed concern that technology may not yet be there to secure this by 2009.

There were other statements made in support of the 1/1/09 date: there was a demonstration by a technology vendor of the ability to read RFID tags through diverse media (fluid, foil) and to read certain tags in a room filled with tagged products along with statements that RFID technology is ready; calls for consumer protection from counterfeit drugs sooner than 2011; comparisons to other industries that have stated they could not be ready for various events by a mandated due date, and yet complied when the requirements remained in place. There was also a presentation on a different and adjunct method to authenticate a drug product at the time it is dispensed to patients.

The members of the board remained adamant on the January 2009 date. They continued to encourage work on pilots that will lead supply chain members to wise business decisions when implementing the requirements, and where possible, share the results of these pilots. However, several speakers expressed concern that such sharing would violate antitrust laws. Deputy Attorney General Room requested such legal opinions so further review on this could be conducted, repeating prior requests by Mr. Room for these opinions.

Technology and software companies indicated that there is knowledge and expertise about how to do this available now, and costs for chips continue to decline.

The committee directed that a readiness template be developed by staff to collect information about progress to date in moving toward implementation, with timelines to identify when implementation would be feasible. This was in response to Deputy Attorney Joshua Room's statements that under California law, the board has the ability to delay implementation of the pedigree requirements until 2011 if the board determines that "manufacturers or wholesalers require additional time to implement electronic technology to track the distribution of drugs within the state." Moreover, the board was advised that it could not extend the deadline without possessing data-based evidence to support an extension. The decision must be based on facts, not statements, and the data must demonstrate that a delay would be in the public interest.

This readiness template was made available on the board's Web site in late December. In this packet are a number of requests for extension in the delay until January 2011. Only some of these requests are in the template format requested, and few provide the information requested. This topic will be discussed a bit later in this meeting.

Inference and Grandfathering

At prior meetings certain industry participants have asked for inference to stand in for item-level scanning at every inbound and outbound transaction (e.g., an unopened case of 24 items could be read once, and inferred that all 24 items are intact if the case is

appropriately sealed), for grandfathering of existing products in the supply chain after the implementation date, and a number of other accommodations.

The board scheduled a discussion on grandfathering and inference at the December 5 Workgroup Meeting. Prior to this meeting, the board had released a different template to collect information from which the board hoped to frame the discussion at this meeting.

However, only EPCglobal provided comments on grandfathering and inference prior to the meeting. These comments were used to frame the discussion (the comments are provided in the back of this tab section as **Attachment 2**).

Additional discussion on these topics will be needed before the board can determine how to proceed.

Questions and Answers on E-Pedigree

The Workgroup was updated on the status of the questions and answers on e-pedigree. In September, the board activated an email address for industry to submit questions regarding implementation issues. The address is californiapedigree@dca.ca.gov.

Staff has developed answers to many of the questions submitted as of mid-November, which are currently at the final stages of legal review by the Department of Consumer Affairs. Staff hopes to release these at some point near the time of the board meeting as guidance to the industry.

E-Pedigree Web Area Under Development

The board's webmaster is finalizing an area of the board's Web site into a single source for e-pedigree information currently found in several places. When completed, there will be a single place that will consolidate or link information on e-pedigree found in various places on the board's Web site

B. Presentations to the Board on the Status of Standards for Electronic Pedigrees

Approximately 10 individuals and entities have requested to present information to the board regarding electronic pedigree implementation.

C. Presentations to the Board Review on Readiness to Implement E-Pedigree Requirements by January 1, 2009

The board has received more than 42 comments from companies and associations on their readiness to implement e-pedigree requirements on January 1, 2009 (at the time this packet was mailed). Some used the information requested by the board in its

readiness template. Others did not provide this information. The submitted comments are provided in a separate tab section in the board packet.

As public comment, representatives of some of these companies and associations will be given an opportunity to briefly discuss their perspectives before the board.

Attachment 1

*Minutes of the Work Group on
Implementation of E-Pedigree
Of December 5, 2007*

Including PowerPoint Presentations



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DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
WORK GROUP ON E-PEDIGREE
MINUTES**

DATE: December 5, 2007

LOCATION: Red Lion Hotel Sacramento
1401 Arden Way
Sacramento, CA 95815

**BOARD WORK GROUP
MEMBERS PRESENT:**

Stanley Goldenberg, RPh, Chairperson
Ruth M. Conroy, PharmD
Robert Swart, PharmD

**OTHER BOARD
MEMBERS PRESENT:**

Susan L. Ravnan, PharmD
Stan Weissner, RPh
Henry Hough, Public Member

STAFF PRESENT:

Virginia Herold, Executive Officer
Joshua Room, Deputy Attorney General
Robert Ratcliff, Supervising Inspector
Judith Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Robert Venegas, Inspector
Janice Dang, Inspector
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst
Michelle Leech, Administrative Assistant

Note: A number of presentations were made to the work group at this meeting. Copies of these presentations follow the minutes.

CALL TO ORDER

Chairperson Goldenberg called the meeting to order at 9:14 a.m. He acknowledged Susan Ravnan, Hank Hough, and Stan Weissner as board members attending the meeting that were not members of the Work Group.

Mr. Goldenberg noted that the agenda was significant and the board would give everyone a chance to speak. He asked the manufacturers in the audience to identify themselves. Some of the manufacturers (and other pharmaceutical industry companies) represented were Amgen, Abbott, Allergan, 3 Rivers, AstraZeneca, Watson, CV Therapeutics, Smith Labs, Bausch & Lomb, Tap, TEVA, Astellas, Mylan, Precision Dose, Johnson & Johnson, Sigma, Slag Allarmed, Sandoz, Wyeth, Apatech, DRX, Biogen, Hospira, Dade, Solstice Neurosciences, GSK, Genentech, Hoffmann-La Roche, Pfizer, Bristol Myers Squibb, Reliant, Schering-Plough, Novartis, Elan, King, Barr, Bayer, MGI Pharma, and Sepracor.

Mr. Goldenberg introduced Diane Furukawa, PharmD, and David Botelho, CPA, as interested parties from the California Department of Health Care Services Medi-Cal Division.

Ms. Herold advised that representatives of the FDA and several other states were participating in the Work Group via conference call speakerphone, but on a "listen-only" status.

PROGRESS OF THE IMPLEMENTATION OF ELECTRONIC PEDIGREES PURSUANT TO THE CALIFORNIA BUSINESS AND PROFESSIONS CODE

1. Presentations and Updates by Manufacturers, Wholesalers, Pharmacies and their Associations on Implementation of Electronic Pedigree by January 1, 2009

- **Alien Technology**

Victor Vega, Director of Technical Marketing, and Ronny Haraldsvik, Vice President of Marketing of Industry Relations, gave a multimedia presentation demonstrating radio frequency identification (RFID) advancements.

Mr. Vega noted that RFID technology has improved greatly. The previous hurdles of reading tags in and on water, and around foil and other metal materials have been overcome. He stated that more than 35 states in the U.S. are considering e-pedigree legislation to enhance patient safety. Combating counterfeit drugs is one of the reasons the pharmaceutical industry is motivated to pursue RFID technology, in part, because of its reverse logistics capabilities.

To perform e-pedigree tracking at the item, case, or pallet level, three technologies could be used: 2-D barcoding, high-frequency (HF) RFID, and ultra high-frequency (UHF) RFID. RFID technology can be used for other wireless infrastructure considerations as well, such as electronic article surveillance (EAS – security), automatic dispense mechanisms, and file management.

Mr. Vega stated that radio frequency exposure has not been shown to affect the potency, efficacy, or stability of biologics or pills.

Some of the challenges of RFID technology have been reading tags in items with water-based content, gel-packs, limited item-level surfaces, small vial diameters, metal or foil surfaces, and shadowing/shading (close proximity of tags to one another). Mr. Vega said that these challenges have been overcome, and significantly smaller RFID tags are now being manufactured as well. Some of the other benefits of RFID technology are improved transportation and logistics management efficiencies. In addition, temperature tag monitoring can be performed using UHF RFID.

Mr. Vega stated that the price of RFID tags has been reduced from about \$1 each to less than 10 cents each. He emphasized that other hurdles have been eliminated including reader collision, short read range, sluggish responses, interference susceptibility, "dumb" readers, inability to filter/mask, unfriendly user interfaces, limited suppliers and support, regional tag design requirements, and wireless access point contention. He added that because of the initiatives of Gen2, companies are no longer held hostage by a single vendor; they can choose from many different vendors.

Mr. Vega emphasized that hardware is no longer an excuse to not adopting RFID technology because Gen2 tags are flexible and scalable. The technology is stable, robust, and reliable, and there have been developments in silicon as well. RFID silicon now has superior sensitivity that works on farther distances, and has extended user memory, and wide spectral bandwidth alleviates regional tag incompatibility. The pharmaceutical industry can use tags that are now less than one square inch, and read ranges of up to 130 feet have been demonstrated. There is a wide selection of tags currently available. "Dumb" tags used to be read-only, but now have read/write capabilities, and at a lower cost. Access control tags that were near-field are now near-field and far-field.

Mr. Vega noted that with EPC Gen2 RFID, you can ask a vendor to program chips with your identifier in the tag. The technology is available today. Other security options include tamper-proof labels and a 32-bit access password that is "lockable." Tag reader technology has also been emerging, with diverse choices available including handheld and forklift readers.

Mr. Goldenberg asked that industry come forward with their comments on this presentation. He asked that everyone limit their comments to the information presented today. He emphasized that the board wants to understand industry's perspective on this issue.

Mr. Haraldsvik stated that they have been working with different vendors, including Wal-Mart, at the case level. He said it has become clear that the whole industry must move forward in order to deploy the infrastructure necessary.

Mr. Goldenberg stated that board is seeking information about the projects being conducted. The board will need a description about the testing, including when it started, and the resources applied to it.

Mr. Haraldsvik responded that they have tagged cases shipped to retail. He said they are still hearing from retailers who are asking where to go. They are not seeing wide deployment of the technology, but their results so far show good data, promising data. He said that they conducted pilots in France on medical devices. They also have 5-10 hospital pilot projects going on in the United States right now.

Mr. Goldenberg asked what they have done to determine whether biologics were affected by exposure to RFID.

Mr. Haraldsvik responded that they have conducted studies and had conversations on the issue, but the jury is still out, and they want FDA's guidance. He stressed that it is important to choose one technology to go forward.

Mr. Goldenberg stated that the board respects that there are alternative technologies, but that California just needs a safe system. We are now on a one year deadline.

Mike Rose, a representative from Johnson & Johnson, commented that they have conducted a number of projects, but they can't rush the technology. They have made a commitment, but California's law doesn't stipulate a specific technology. Johnson & Johnson is committed to complying with the law, but it is challenging. They have teams working on it, though.

Mr. Room asked whether it was a fair assessment that in 2003 or 2004 RFID technology was not as developed, so they were leaning toward 2-D barcoding instead? He asked if their level of RFID study was somewhat forestalled if it was a couple years old.

Mr. Rose stated that they were driving towards 2-D matrix, and they want it to work in other jurisdictions, including Europe. They have an RFID lab and their work is up-to-date. They believe RFID will have a place and they'll continue to look at ways to adopt that technology, but their use cases are quite different.

Mr. Goldenberg stated that the issue is not "us and them" and that we are all trying to understand the details of the issue. The Enforcement Committee's responsibility is to give a report to the full board on the issue, and information is needed in order to make good decisions.

Lou Kontnik, Director of Brand Protection and Business Continuity for Amgen Pharmaceuticals, stated that Amgen offers a narrower range of products, and the issue of biologics and suitability is the threshold focus.

Mr. Goldenberg noted that more than two years ago, we were discussing this same issue.

Mr. Kontnik responded that Amgen has given taken the matter seriously, and looked in-depth at RFID. Most of their products are biologic, and they have conducted studies on

exposure to their products. Equivocal results have been shown, and in at least one case, they saw a statistically significant difference of the product after exposure to RFID. He said the real issue they're following is that there is not an established and accepted FDA protocol for products. They don't have clarity about safety or a regulatory approach as to whether their products are affected by RFID exposure. He said the work they are doing includes 2-D barcodes, as is Johnson & Johnson. They hope to share information about that work with board shortly. Amgen wants to protect patients, but at the unit level, their work has only been done using 2-D models.

Peggy Staver stated that Pfizer has been doing pilot work since 2004, tagging Viagra at the pallet level. They have been using Alien Technology tags at the unit level and case level. She noted that Pfizer expects to tag and ship Celebrex by the end of December. She said that statements that all issues surrounding RFID technology have been resolved is misleading, and they are still looking at looking at both 2-D barcoding and RFID.

Mr. Goldenberg asked what would happen in one year, if Pfizer's decision was still up in the air. He likened it to revving an engine, but not moving forward.

Ms. Staver responded that as stated to the committee in June 2007, they expected it to take 5-7 years to serialize all their products. She said they would work with industry to see what will work across the supply chain to ensure patient safety and channel security. She said it's not that Pfizer isn't doing anything, it's just very different what they're doing in the U.S. verses what they're doing in Europe.

Mr. Goldenberg said that we just heard a presentation about the advancements of technology, and the board wants a sampling of how manufacturers are dealing with this information.

Jim Dowden, representing Hoffman-La Roche, said he had some impressions of Victor Vega's presentation. He said that Mr. Vega said the right things, but that tagging is just one part of the picture. Mr. Dowden said that you have to bring IT structure and other things into play.

Mr. Dowden stated that Hoffman-La Roche did an initial pilot at the case level in 2003, and tracking at the case level was promising at that time. Their next level of activity was tracking at the item level using vials, blisters, and bottles. They looked at different frequency technologies, and learned that blister packs and vials were a little tricky, and that solid dosage bottles were the least tricky. He emphasized that it's not just about putting a tag on something. They looked at the orientation of tags and other nuances of RFID technology at the case level. On the item level, they have not done quite as much work.

Mr. Goldenberg asked if there were any further questions about the information presented, before they returned to Alien Technology's presentation. There were none.

Mr. Vega noted that there is reader diversification in three categories:

1. OEM modules, adapters, and sensors
2. mid-tier fixed
3. high-end fixed

Mr. Vega stated that a cell phone is much like a reader. He added that Intel and Samsung are silicon leaders, which suggests strong industry stability.

Mr. Vega referred to the attributes of Smart Antenna (ALR-9650) and the High-Performance Enterprise Reader (ALR-9900). He performed a demonstration using the ALR-9900 reader. He said that the cost of readers have dropped to as low as \$600 during the past two to three years. He stressed that the stability and performance of readers was poor, but now it's very good.

Mr. Vega stated that downstream partners are driving this industry. He demonstrated the choice between adopting multiple technologies verses one technology by showing a graphic of a large man bulging at the midsection standing next to a slim man. He added that Alien Technology white papers could be downloaded at <http://www.alientechnology.com/whitepaperdownload/>.

Mr. Vega conducted a demonstration of UHF RFID technology with the objective of showing how technology has advanced. His demonstration showed how RFID technology worked, even under the following conditions:

- Tags in close proximity to one another (shadowing)
- foil blister packs and other products with metal foil
- tags read through and on containers of liquid (water)
- very small vials

Mr. Vega also demonstrated that UHF RFID technology could identify tampered cases and out-of-date products using a hand-held device with an OEM module. His demonstration also included holding bottles with 2-D barcoding in front of a scanner. Each bottle needed to be placed in front of the scanner, one at a time. He emphasized that manpower is not cheap, and reading each bottle would take some time. He then placed a case of RFID-tagged bottles in front of the scanner. Scanning the box showed that 25 bottles were contained in the box. Mr. Vega conducted other demonstrations with blister packs of Benadryl and NyQuil, plastic bottles of Crystal Geyser drinking water, and paper files of different colors.

Mr. Goldenberg stated that the board understands that the technology has advanced, but needs to know how to operationalize the technology. He said we are meeting in the spirit of working together to understand the progress made on the technical side, as well as on the operational side.

Mr. Room noted that questions have been raised in prior meetings about the availability of tags and readers necessary for industry-wide rollout. He asked whether Mr. Vega could comment on the current manufacturing capacity.

Mr. Vega responded that the industry would certainly welcome it, and it's not just about Alien Technology. There are other providers that can ramp up manufacturing right away.

Mr. Room asked about the Department of Defense (DOD) tagging products for defense contractors. He noted that the DOD had 2007 implementation guidelines.

Mr. Haraldsvik said that they are currently working with the U.S. Navy, Air Force, and Marines on projects.

A person from the audience asked whether the military projects are serialized at the unit level, and noted the magnitude of program expenses to conduct these pilot projects.

Mr. Haraldsvik responded that it is at the case and pallet level right now.

- **California Pharmacists Association (CPhA)**

Mr. Goldenberg introduced Kathy Lynch, and asked that the pharmacy community tell the board where their challenges are.

Kathleen Lynch, Esq., Vice President of Government Affairs, emphasized that CPhA members are solution driven and most importantly, they are advocates for patients. She said that as pedigree legislation comes into play, CPhA doesn't know when pedigree will be ready at the pharmacy level because of several issues including equipment, space, budget, and training personnel. She said pharmacies are totally reliant on their upstream partners as to which technology will be used. Different costs estimates have been provided to them including \$25,000 to \$30,000 per store to ramp up and comply with California's e-pedigree law. Will one reader be needed at each pharmacy, or two readers capturing 2-D and RFID? What about the cost of software? Who will house the software? She also said they need guidance from the board on inference.

Ms. Lynch said that questions about grandfathering also present an issue. For example, if they have stock on hand on January 1, 2009, what about products received from upstream partners after January 1, 2009 without pedigree? They rely on their upstream partners, and last minute decisions will affect them.

Ms. Lynch stated that CPhA has been working towards pedigree compliance by educating their members, meeting with wholesalers, and participating in pilot programs. Pedigree is not the only issue facing their members, though. Other issues they will be dealing with are implementation of AMP, tamper-resistant prescription pads, new

labeling requirements, health care reform, drug disposal programs, and Medicare Part D. All these issues put enormous pressure on independent pharmacies.

Ms. Lynch referred to the visual display of nesting Santas from Ms. Herold, similar to Russian nesting dolls. She said that although the smallest Santa is the manufacturer and the largest Santa is the retail pharmacy at the end of the supply chain, CPhA members actually feel small instead.

Ms. Lynch stressed that CPhA members want to comply with the law, and she recalled only around 10 people in the audience when these meetings first began. Now there are many more people involved, but there is still much work to be done.

- **National Community Pharmacists Association (NCPA)**

David Wilcox, owner of an independent pharmacy, advised that he was representing NCPA, and he thanked the board for the opportunity to testify. He said that NCPA members represent 23,000 pharmacies, 75,000 pharmacists, and 300,000 employees. He said that millions of patients rely on their members for their prescription care.

Mr. Wilcox emphasized that NCPA members do not believe the January 1, 2009 deadline of pedigree is possible to achieve. He said that there are circumstances beyond their control including the lack of standard technology implemented at the manufacturing and wholesale level.

Mr. Wilcox stated that NCPA is supportive of a safe chain of custody of drugs to minimize illegal diversion of drugs as well as counterfeits, but their number one concern is standardization so that retail pharmacies will not be forced to maintain multiple technologies. California's law requires capability between all distribution channels, and without standardization, costs could be \$10,000 to \$40,000 per location. Without the state supporting that financial burden, it constitutes an unfunded mandate.

Mr. Wilcox advised that a delay in pedigree implementation is justified, and that NCPA is requesting that the board extended the pedigree implementation deadline to January 1, 2011. He further stated that e-pedigree technology is not ready for purchase and operation at an affordable price, and the public would be best served by delaying implementation to ensure a system that will prevent counterfeit drugs from entering the system.

Mr. Wilcox suggested that independent pharmacists be compensated for the costs associated with the purchase of multiple technologies. He also said that NCPA supports grandfathering so that pharmacists can be dispense drugs up to one year after pedigree implementation. In addition, they are asking the board for a hold harmless provision if inference is part of the process.

Mr. Wilcox said NCPA members are very concerned about costs put on to pharmacists at the retail level. He referenced P.S. 110-085, Sec. 913 that will require the FDA to develop a standardized numerical identifier by March 2010. If independent pharmacists implement a California standard in 2009, they may face a different federal standard in 2010.

Dr. Swart acknowledged that the board understands the end user at the pharmacy level is a dumping pool of upstream partners, and the board would look at the issue of grandfathering.

Mr. Goldenberg thanked Mr. Wilcox for his presentation. He said that the key factor we need is a timeline ensuring that the consumers of California will be protected. We are all in this together to protect consumers, and our worst nightmare will be body count legislation. People will be hurt while waiting. He said we must protect consumers and move forward to a safer line of pharmaceuticals.

Dr. Swart warned that a "timeline" does not mean 5-7 years, which really means never. He said he would feel terrible if people died because there was no sense of urgency.

- **Generic Pharmaceutical Organization (GPhA)**

Shawn Brown, Director of Policy for GPhA, thanked the board for the opportunity to make a presentation. He said that GPhA's members manufacture more than 90 percent of the generic medicines dispensed in the U.S., and that generic medicines comprise 63 percent of all prescriptions. Mr. Brown said that public health is sustainable through generics.

GPhA recognizes that counterfeit products entering the U.S. supply chain would pose a serious threat to public health. The U.S. drug supply is approximately 1 percent or less counterfeit, and 10 percent worldwide. Mr. Brown stated that generics are not likely targets for counterfeits, and no instances have been reported during the last five years. He said that generics compete on price and that is the benefit of competitive market, whereas other countries have price controls.

Mr. Brown noted some of GPhA's efforts toward pedigree compliance included conducting a survey of GPhA members, and working with Wal-Mart in package-level serialized products on a subset of SKUs.

Mr. Brown said that GPhA's economist supplied serialization start-up costs, with a conservative estimate of \$500 million for equipment needed to modify packaging lines of generic producers (i.e., middleware, testing new packing lines, etc.). Item level serialization adds costs to the production of individual packages. Serialized labels will be more expensive than those currently in use. He said that labels with RFID technology are 24-30 cents more than labels currently in use, and labels with pre-printed 2-D barcodes are 2-3 cents more than labels currently in use.

Mr. Brown stated that generics have narrow profit margins on products, though they have higher volumes. Whatever affects the generic market will have direct repercussions on public health and access to affordable medicine in California and throughout the U.S. Unit level serialization on generics will have competitive disadvantages, ultimately resulting in fewer competitors and less competition. Wholesalers have informed manufacturers that they expect products to be pedigreed and serialized by June or July of 2008.

Mr. Brown stated that unit level serialization will significantly increase the production cost of generic medicine, and large-scale withdrawal from the market of low-cost/low-margin products is possible. Case or pallet level pedigree would cause fewer interruptions. He asked whether unit level serialization was shown to counter counterfeit drugs.

Mr. Brown emphasized that there is a lack of agreement among stakeholders on one technological standard that will support interoperability, and that the cost of "experimentation" is not an option. There is no guidance for implementation of track and trace as there is currently no agreement on EPCIS usage. He also referred to possible consumer/patient privacy issues, and whether vendors have the technical expertise to implement and manage the IT infrastructure by January 1, 2009.

Mr. Room emphasized that terminology is important, and that e-pedigree serialization means tracking at the unit level, not case or pallet level.

Mr. Brown stated that access to low cost generic medicine is at risk because high implementation and operational costs of pedigree requirement will raise production costs. He said that GPhA encourages an industry-wide review of the weak points in the pharmaceutical supply chain. GPhA does not believe industry can implement unit level serialization widely by January 1, 2009.

Dr. Swart asked Mr. Brown about studies they've done.

Mr. Brown responded that challenges to implementation are holding the process up. Generic manufacturers can't talk about a single solution because these documents would violate anti-trust laws. They want to see how pilots play out, but will come back to the board with findings when their economist looks at the pilot studies. They expect to come back to the board with their findings in Spring 2008.

Dr. Conroy noted that GPhA's economist is saying what it will cost to do pedigree, but doesn't offer a timeline as to when it can be done.

Mr. Goldenberg asked about the total sales of generic medicine.

Mr. Brown said that generics represent 65 percent of total national sales, but he doesn't have a dollar figure. He said they would come back to the board with information.

Mr. Goldenberg noted that hard data should be provided.

Mr. Room asked about Mr. Brown's suggestion that there is a market disadvantage caused by the need to segregate products compliant with pedigree.

Mr. Brown clarified that he meant to say that California's requirements are the most demanding. A product meeting California's requirements could be distributed anywhere. Products not meeting California's requirements could not be distributed in California.

- **Three Rivers Pharmaceuticals**

Christine Sheehy, Vice-President of Operations for Three Rivers Pharmaceuticals, stated that patient safety is their number one priority. Three Rivers supports state and federal legislation to ensure supply chain security, but is overwhelmed by the complexity of the technology.

Ms. Sheehy stated that Three Rivers Pharmaceuticals contracts out to third party operations for their manufacturing/analytical/packaging; it is not done in-house. Ribasphere Capsules in the 200-milligram dose is their flagship product.

Ms. Sheehy said Three Rivers is at square one, with regard to their pedigree readiness strategy. They are still trying to understand the requirements and monitor the development of standards. Three Rivers has an IT staff of only three people. They work collaboratively with vendors, customers, and trading partners. Though a small company, Three Rivers doesn't see pedigree as an insurmountable challenge, but they must develop a standard, cost-effective solution. They would have to integrate an e-pedigree solution with a validated distribution system, and there is a lot of work to be done in that area as well.

Ms. Sheehy said that CFR 21 requires distribution records; you must test distribution processes so that you have accurate records throughout the process. For those records, they must write test scripts and final reports, which take several months. She referenced an April 2007 FAQ document with a question as to how a sample implementation would work for a small company. She said it's a mouthful to implement in 12 months.

Ms. Sheehy said that the State of California is driving industry to what will become a national standard. The challenge for Three Rivers is that trying to comply with e-pedigree initiatives will consume 100 percent or more of their 2008 IT budget. There is a wait and see approach, and they'll have to be on the same page as everyone on both sides (suppliers and customers). They are also getting direction that whatever money they spend in 2008 will have to be for technology for the long-term solution.

Ms. Sheehy said Three Rivers is concerned about understanding the requirements, and they can't send three IT people around the country learning. They have great vendors, but it takes time to work with vendors as well.

Ms. Sheehy reiterated that patient safety and the security of the supply chain is their priority, but they respectfully ask for an extension. She added that they have not done pilot studies, as there has not been time to do so.

Mr. Room asked how their contract manufacturing was set up, and whether they were exclusive to Three Rivers.

Ms. Sheehy responded that they use two contract manufacturers, and Three Rivers is small fish to them.

Mr. Goldenberg asked whether there is an industry group representing outsource manufacturers. Three Rivers is like a boutique firm, and the board considers small companies to be an integral part of this process.

Ms. Sheehy noted that Contract Pharma Magazine could identify different outsourcers.

Mr. Goldenberg asked Ms. Sheehy to forward information about the magazine to Ms. Herold.

Mr. Room stated that there is a lot of information as well as disinformation out there regarding anti-trust. He invited anyone with opinions given to them by counsel be shared with him, and he'll see what can be done to provide clear information. It will be helpful to drill down on actually what the anti-trust restrictions are on communications.

- **TEVA**

Brian Shanahan and Michelle Keller appeared representing TEVA Pharmaceutical. TEVA supports the goal of securing the integrity of the pharmaceutical supply chain to ensure provision of safe prescription drug products to the public. TEVA is the leading generic pharmaceutical company in the world, with the largest pipeline in the industry. TEVA has 8 U.S. manufacturing sites, 8 international sites, 68 unique internal packaging lines, 50 outsourced manufacturers, 5 contract packagers, and 1 U.S. distribution site. They depend on a seamless distribution network.

Ms. Keller stated that TEVA complies with existing federal and state-level pedigree laws, and they seek standardization of supply chain integrity and track and trace interoperability. They are concerned that early adopters risk investing in technology that may not prevail. Some of the challenges of item-level serialization include:

- Lack of unified standards for track and trace interoperability
- Long implementation timeline

- Disruption to ongoing operations
- Significantly more expensive than lot-level e-pedigree

Mr. Shanahan emphasized the impact of requiring item-level serialization and track and trace capability on generic manufacturers, and that it will increase the production cost of generic medicine to patients. He said that generic manufacturers have lower revenues and profits and are, therefore, less capable of absorbing such costs. Generic manufacturers may be forced to increase prices or even discontinue certain product lines. Mr. Shanahan stressed that patients receive treatment with generic medicines that they would not otherwise be able to afford.

TEVA's actions to date include forming a global, interdisciplinary project management team specifically focused on compliance with California pedigree. They are also planning to conduct pilots with wholesalers, chain drug stores, third party manufacturers, private labelers, and re-packagers. TEVA does not have a pedigree implementation timeline, though they report that they are formulating one. They noted various challenges to formulating their timeline including equipment availability and potential labeling changes. TEVA reports that because their customers are imposing multiple requirements and there is no agreement about standards, they are "stuck." An estimated figure of \$35 million to install equipment capable of 2-D serialization on packaging lines was given, but did not include the costs associated with distribution centers or ongoing operating.

Mr. Shanahan concluded the presentation by stating that TEVA supports a multi-faceted, risk-based and phased-in approach involving business practices, legislation/regulation, enforcement and technology to address issues that impact patient safety. They asked the board to postpone, as soon as possible, implementation of the California Pedigree law to ensure a continued supply of generic to citizens of California and to enable the industry to adopt a standardized system at a reasonable cost.

Dr. Swart asked about TEVA's annual sales.

Mr. Shanahan responded that it is \$8 billion globally.

Dr. Swart noted that, on a percentage basis, the cost to implement is not as onerous, looking at it on a grand scale.

Mr. Shanahan stated that they are not limited just to implementation costs. They want to put capital resources into something that will work with everyone in supply chain.

Mr. Goldenberg stated that the board understands the Beta/VHS challenge, about selecting the technology to carry out e-pedigree requirements.

Mr. Room said this comment was for everyone present because it's about timing and attention to the issue. Statements made today by some of the presenters didn't strike him as anything that couldn't be said two years ago. He also wanted to correct a

misperception – the initial law required unit level serialization. So there is nothing new. The board has only given more structure to the law with the 2006 amendments.

Mr. Room stated that he has repeatedly advised the board that they must have a factual record of what the obstacles are and what industry has actually done, so the board can take into account whether a delay is in order. The board cannot delay the implementation date without those specifics and if a good faith effort cannot be demonstrated.

A person from the audience stated that by Spring 2008 they would have the results of a pilot study conducted.

Ms. Herold noted that there were early adopters who have moved forward and did not hold back implementation and pilot studies.

Mr. Goldenberg stated that if the board moves without a conviction to the January 1, 2009 implementation date, we will be sitting here talking about the same thing in 2011, 2013, or 2020. The board is clear in its needs. If TEVA has other information to present, he asked that it be forwarded to the board before the next general board meeting.

- **Watson Pharmaceuticals**

Mary Woods, Executive Director of Call Center Operations for Watson Pharmaceuticals, thanked the board for the opportunity to speak. She said that Watson is committed to patient safety and they do not take the matter lightly. Ms. Woods gave an overview of Watson's corporate profile. Watson is the third largest supplier of generic pharmaceutical products in the U.S., based on prescriptions dispensed.

Ms. Woods stated that Watson's actions to date regarding e-pedigree include a two-year RFID pilot with a Watson customer. The pilot included a modified packaging line, UHF Gen1 and Gen2 RFID pre-serialized labels, scanners, readers, and licenses. She said these actions show their significant commitment to technology.

Ms. Woods said the challenges they see include standards that are still being developed, and timeline constraints for equipment installation, testing, and validation. She said it's not just the cost element; it's trying to get technology decisions to be made just once, instead of over and over again. Watson has 32 packaging lines and their vendors have advised that they cannot have their packaging ready in time to be compliant.

Ms. Woods said that Watson's next steps toward e-pedigree implementation include trading partner testing. They asked the board to consider an extended implementation date to ensure that standards are in place and to protect the integrity of the supply

chain, while continuing to provide lower cost alternative pharmaceutical products to patients.

Mr. Goldenberg asked Ms. Woods if Watson had any information to share with the committee as to when they could comply.

Ms. Woods responded that they will have a "timeline for a timeline," but only if they have the standards. She said it was a Catch 22 until they agree on data collection and methodology. At that point, they can "work backwards into a timeline" but until then, they will get stuck in loopholes. Ms. Woods said their customers were confused as well, and they are reaching out to them. She said it saddened her to see so much confusion.

Mr. Goldenberg asked whether Shawn Brown could help Ms. Watson prepare something for the January 23, 2008 board meeting. He suggested that Shawn get information from their constituents regarding the timeline of the timeline. He emphasized again that we do not want to be talking about the same thing in 2020, and that any information to present on January 23rd should be sent in advance for inclusion in the board packet.

Mr. Room stated that the board would agendaize all requests for delay of implementation, and all requests must be submitted in writing. Requests must be supported by data demonstrating compliance efforts thus far, including compliance studies, what that particular segment of the industry has done, and when that segment of the industry will be compliant. A request to delay must show what the requester has done so far, what steps will be taken, what products are in their portfolio, and the logical requirements to modify their packaging line. Mr. Room asked Mr. Brown what data was submitted to their economist.

Mr. Brown responded that he couldn't give specific information on companies. He said there is fierce competition among companies, and that's why they didn't aggregate the information.

Mr. Room said that the decision the board will make must reflect their duty to provide the highest degree protection to the public. To delay implementation, the board must be satisfied that the technology is not ready. To secure an extension, the board needs data demonstrating that another date is a more appropriate date than January 1, 2009. If the cost would be prohibitive or supply would be interrupted, that must be specifically spelled out in the request.

A person from the audience asked the board to provide a template for the requests. She said that they want to give the board the information in a collaborative spirit, and a template will advance their ability to give the board the information it needs.

Ms. Herold said a template would be posted on the board's Web site.

Mr. Room said that in the last 10-12 months the board has been clear about the data that the board will need to delay implementation.

Mr. Goldenberg stated that we've all been working together very hard on this, and it is one of the priorities of the board. The board cannot justify a delay without information, and cannot place the consumers of California in harm's way. This is a significant meeting today, and January 23, 2008 will be a watershed meeting.

- **Pharmaceutical Research and Manufacturers of America (PhRMA)**

Marjorie Powell, Senior Assistant General Counsel for PhRMA, presented findings from a survey of their members. PhRMA is a trade association representing research-based pharmaceutical and biotechnology companies in the U.S.

Ms. Powell stated that PhRMA conducted a survey to determine what pilots their members had done. She said they did not send the survey to all their members because they did not have correct contact information for all of them. They sent the survey to the companies they knew were actively working in the area. The survey asked questions about e-pedigree without serialization and with serialization.

Ms. Powell said that PhRMA received responses from 21 companies, 16 of which have been engaged in pilot studies. For pilots conducted at the item level, these companies used 2-D barcoding. The majority of the companies tagged a limited supply of a particular product.

Ms. Powell advised that she would compile information from the survey and provide it to the board in a letter, prior to the January 23, 2008 meeting.

Ms. Powell noted that the survey revealed a number of issues regarding exchange of information. She said those issues need to be worked out because it's like peeling an onion where each layer shows subsequent issues. Ms. Powell referred to the nesting Santas and Russian dolls as an example. If a pilot is conducted with the first two entities, the decisions at the first and second level could cause problems at the third and fourth levels. Companies must change their processes, including software and computer systems.

Ms. Powell said that entire packaging lines could be out of use for two to four months during modifications. Companies must get FDA approval for changes in packaging lines, so FDA resource issues will occur. They have been in contact with the FDA to identify what resources will be needed, but modifying one packaging line does not readily translate into faster implementation in other packaging lines. Three to four years of pilot projects show lot level itemization, is enough to authenticate products in the distribution system.

Ms. Powell said that to avoid dealing with the same issues in the year 2020, PhRMA urges the board to think about a system that involves everybody in the distribution chain, including the downstream partners. They suggest fewer details initially, starting with lot level or case level, tagging, then moving to unit level serialization. She said it would be best to phase in this process to eventually get to unit level serialization, starting with those products with the greatest risk.

She asked the board to consider a timeline looking at high-risk products by a certain date, and lower risk products at later dates. She said that high-risk products included both patented and generic products.

Ms. Powell questioned the effect of RFID on biologic products, and how testing should be done on those products. She noted that there could be a problem if they go forward with RFID and effects are later shown on biologics. She urged the Enforcement Committee to give FDA the benefit of everything learned because California has moved more quickly than the FDA. In the end, there must be a uniform system, not just one system for California, and for the country.

Ms. Powell said she would get back to the board with more details, but not necessarily a timeline for all companies. She said that in response to Mr. Room's request for copies of opinions about antitrust issues, she would forward to him information that she is waiting for from their antitrust lawyer.

Mr. Goldenberg thanked Ms. Powell, and said he looked forward to the information she will provide for the board's packet. He advised that all board members receive meeting materials for their review, prior to the public meetings. Part and parcel of that review is a full disclosure of information that is understandable by professional members of the board and public members of the board. He suggested it would be helpful if information presented to the board is in English, instead of pharmaceutical or legalese.

Ms. Powell stated that PhRMA wants to prevent patients from products that are counterfeit, but the focus at the manufacturer level should be on high-risk pharmaceuticals.

Mr. Goldenberg asked whether PhRMA had a person dedicated to this issue, due to their importance to manufacturers.

Ms. Powell responded that there is not a particular person that she knows that is dedicated to this issue. She said that PhRMA asks their members to work on various committees, and PhRMA has had a technical committee working on this issue for five years. That committee is comprised of companies that have resources, but she doesn't have a contact person to reach out to. She said they extended the time for their members to respond to the survey because all of their member companies have an interest in pedigree, but do not necessarily have someone working on it.

Mr. Goldenberg noted that the board looks to PhRMA to help the board understand, and he understands that the FDA has resource issues. He is hoping to receive information from the FDA as well.

Ms. Herold noted that with respect to risk-based products, some of PhRMA's members have already tagged products, but those products can only be read by certain people. She added that some companies have already done risk-based assessments and in the absence of any requirements, they are already doing a number of things to protect their drug products. She added that industry advised the board in 2006 that they could readily tag products at the case and pallet level and asked whether this first step had been taken.

Ms. Powell responded that she was not sure how to answer, but she is aware of two companies with tagged products at the unit level, one of which was read all the way down to the pharmacy level.

Mr. Room noted that at the time of enactment of this legislation, PhRMA members said they didn't want a list of "dirty" drugs. If the board adopted a risk-based approach, which would require legislation, what drugs would be on that list? How could the board allocate the costs if some companies had multiple drugs while others had none – manufacturers without high-risk drugs, would they be expected to share in costs anyway? What criteria could be used to develop such a list and would all PhRMA companies support the resulting list? Would the board legislate that list? Would each manufacturer volunteer three drugs to place on the list? Are PhRMA members willing to do that?

Dr. Swart commented that pedigree only for certain drugs would definitely affect end users. In the pharmacy, they would have to check some drugs but not others, which would be problematic.

- **Pfizer**

Peggy Staver, Director of Trade Product Integrity for Pfizer, stated there are a couple companies that have serialized SKUs. For example, Viagra can be read with HF and UHF. Albertson's has stores in the Chicago area that were reading tags at the pharmacy level, and at one point Rite-Aid was involved in a pilot as well.

Ms. Staver stated that in order to read the serialized tags, a pharmacy would have to have access to their system and have an account. It will enable a company to read, but not to authenticate back. Pfizer does not have agreements in place with anybody. She added that serialization requirements are different than pedigree requirements.

Ms. Herold suggested that field tests could be conducted, but she heard from the pharmacy end that nothing is coming through that they could pre-test. As a result,

pharmacies can't train their staff, though this would provide a perfect opportunity to do so. She asked that Pfizer take an extra step further to see how it will work in California.

Ms. Staver responded that Pfizer will need to work with each trading partner, aligning with each trading partner from end to end to implement e-pedigree.

Heather Zenk, from AmerisourceBergen, commented that authentication of a serial number is different than a chain of custody.

Mr. Room asked for clarification as to whether they are accessing data, not adding to the data.

Ms. Zenk responded, yes, they are accessing the data only.

Ms. Staver said that Pfizer is hearing from companies that are reluctant to make a significant investment in technology until there is common agreement.

Ms. Herold asked whether a pharmacy could request access from Pfizer, and Mr. Room asked whether access would occur through a web portal.

Ms. Staver responded yes to both questions. On a separate issue, Ms. Staver stated that manufacturers know best which products are best identified as high-risk.

Mr. Room said that his comment was not directed just to Pfizer, but that companies can generate a list of high-risk products and it shouldn't be that hard. His advice to the board is that it is not sufficient for the board to identify criteria for a list, but an actual list would have to be developed. It would result in a huge issue for litigation, and the board would not want to litigate each drug applied to a list. He added that regarding common agreement about technology, as the board and staff have repeatedly advised, companies do not want the board to legislate which technology should be used.

- **Distribution of Revenue for Filled Prescriptions in 2006**

Ms. Herold provided information and statistics from a report provided by NACDS. A chart from the report showed that the average cost of prescription drugs dispensed during 2006 was \$68.26. This was for brand name and generic drugs. The chart revealed that 77.6 percent of the cost of a filled prescription (\$52.97) went to manufacturers of which \$8.58 was net profit and wholesalers made an average profit of \$0.72 for each sale, and pharmacies made \$0.96.

Ms. Herold cited other statistics the NACDS report including:

- 3.4 billion prescription drugs were dispensed in the U.S. during 2006
- Average price of a generic drug dispensed in the U.S. during 2006 was \$32.23

- 54.3% of all prescriptions drugs dispensed in the U.S. during 2006 were generic
- Average price of a brand name drug dispensed in the U.S. during 2006 was \$111.02
- 45.7% of prescription drugs dispensed in the U.S. during 2006 were brand name
- Average price of a prescription drug dispensed in California during 2006 was \$76.72

- **California Health Care Institute (CHI)**

Mike Carpenter presented results of a survey of CHI members. CHI is a statewide trade organization representing the life sciences industry. Mr. Carpenter said that CHI advocates for policies that promote medical innovations, access to the best medicines and therapies, and the health and well being of patients.

Mr. Carpenter stated that a survey of their members was conducted in conjunction with the Biotechnology Industry Organization (BIO). The purpose of the survey was to get a picture of what their members are doing to get ready for implementation of e-pedigree.

The results of the survey revealed that 71 percent of their members had begun some type of "planning" for e-pedigree, but they are facing many challenges. For example, they cite no consensus among supply chain members regarding RFID technology vs. 2-D barcoding. There is concern about setting up the infrastructure necessary (data storage and ownership issues), and whether there is time left to meet the implementation date. Regarding production, there must be a continuous supply of products while packaging lines are being reconfigured for unit level serialization.

Mr. Carpenter also noted concerns about third party business partners because a majority of CHI members rely on third party manufacturers, packagers, labelers and carton suppliers to get their products into distribution. Cost is also an issue for smaller companies because product serialization at each step of the drug distribution chain will require significant upfront and ongoing costs, and they must dedicate human resources to that effort.

Mr. Carpenter's summary of the findings revealed that only 10 percent of respondents believe they can be prepared to implement serialization across all or some of their product lines. The vast majority of respondents are only in the planning phase. He emphasized that CHI members support the law's goal of product integrity and patient safety.

Mr. Goldenberg noted that the companies that CHI represents are the small research companies for different diseases. He asked whether the ownership of these companies was in part by large pharmaceutical manufacturers.

Mr. Carpenter responded that he did not know.

Dr. Swart noted that this group of companies produces the products that are probably at higher risk to have counterfeits.

- **Healthcare Distribution Management Association (HDMA)**

Liz Gallenagh, State Government Affairs Senior Director of HDMA, commended California in trying to facilitate progress towards e-pedigree. She said that the California model offers the best framework and will preserve the integrity of the supply chain, but HDMA has concerns about the robustness and the timeline.

Ms. Gallenagh said that much progress has been made and that there is better software and hardware available now. Supply chain partners have been discussing track and trace, but they need to understand more in order to achieve track and trace and comply with California law. HDMA has helped design pilots, but they need more time to do testing. Products have been tagged by manufacturers, but they are just now testing the storage and collection of information.

Ms. Gallenagh said that HDMA would submit their recommendations to the board regarding inference and grandfathering issues. She emphasized that HDMA continues to try and work through these obstacles, and they must work with their supply chain partners to get more data to the board. If the board grants an extension, HDMA wants the board to act sooner rather than later.

Mr. Goldenberg asked whether she had any thoughts regarding implementation issues for all drugs vs. implementation for only a few drugs.

Ms. Gallenagh said that when talking about implementation for high-risk drugs vs. full implementation of everything at once, the systems put in place for a limited numbers of products would require the same systems that would be needed for full implementation.

- **EPCglobal**

Bob Celeste, from EPCglobal North America, provided an update on standards. He noted that item level tagging for the EPCIS system is in its second 30-day intellectual property review.

Mr. Goldenberg commented that the graphic presentation from EPCglobal is an example of what would be useful to the board to make an informed decision.

Mr. Celeste spoke about the pedigree messaging standard, item level tagging, serialization, supply chain integrity, and track and trace, and tag data standards. He noted that the GS1 Healthcare taskforce would be assembling.

Mr. Celeste emphasized that the EPCglobal pedigree messaging standard is the only ratified standard that meets FDA, Florida, Nevada, and California pedigree requirements. He outlined what information is contained in a drug pedigree. He also spoke about EPCIS events, and that they answer five questions (who, what, when, where, and why). He also spoke about possible recommendations including U.S. guidelines or a global standard for how to use both the pedigree messaging standard and EPCIS to satisfy pedigree regulations.

Mr. Celeste stated that EPCglobal is working on the assessment on how the pedigree messaging and EPCIS standards will be interoperable.

A person from the audience asked whether the board accepts EPCIS as a tool to meet pedigree requirements.

Ms. Herold responded that this is what EPCglobal is working on.

Mr. Room added that it appears that the infrastructure allows trading partners to pass information, but we don't know if that meets the interoperability requirement. The board is not here to endorse any particular technology solutions.

- **Aegate**

Graham Smith and Gary Noon gave a presentation regarding an electronic product authentication system used in some countries in Europe. Mr. Noon emphasized Aegate's commitment to patient safety and stated that the current distribution system is not conducive to patient safety. They have approached patient safety from a different point of view because they are looking at pharmacies, and authentication of drugs within the pharmacies before a product is dispensed to a patient.

Mr. Noon stated that complexities exist with the current e-pedigree approach because of the requirement to establish e-pedigree for each saleable unit inside a pack/case inside of a pallet. He emphasized the need for standards because we are using new technologies that are unproven.

Mr. Noon stated that authentication and case level e-pedigree could help resolve these complexities until the technology is implemented by the supply chain. He described authentication as the process to verify at the point of dispensing that the goods being dispensed have the same manufacturer's identifier displayed as present on the secure data base provided by the manufacturer.

Mr. Noon stated that manufacturers can mass serialize the products and provide this data into a central database. Later in the pharmacy in real time, a pharmacist scans the product, which doesn't interfere with pharmacist's workflow because he/she already scans the products. Data is sent back in less than one second during scanning and if something is wrong (i.e., out of date drug, recalled drug), an 'alert' will display via a screen prompt. The pharmacist must touch the screen to acknowledge the alert. This process has resulted in expired medicines being identified in Belgium.

Mr. Noon stated that 18 major pharmaceutical companies are currently involved with the authentication of drugs, with 1,300,000 authentications being performed each month in Europe. In Belgium, 5,300 pharmacies are participating; in Greece, 9,500 pharmacies, and in Italy, 17,400 pharmacies are currently performing authentications.

Aegate reported that pharmacists find the drug recall and expiration information provided during authentication very useful. Products have been intercepted during this process, preventing recalled products from reaching patients.

Aegate proposed that if every saleable unit is authenticated in the pharmacy, and inference between case level and the saleable unit can be justified, then the existing legislation requirements can be met with their system. To make that approach happen, however, California's Board of Pharmacy would need to accept the principle of inference from case level to saleable unit, provided it is supported by authentication in the pharmacy. He added that California's Board of Pharmacy would also need to endorse a coding standard, such as GS1.

Mr. Noon suggested formation of a task force to evaluate this proposal and generate a road map. The working party of the task force would consist of solution providers, manufacturers, wholesalers, pharmacy chains, and Board of Pharmacy representatives (as an observer). He recommended that the task force, if formed, report back to California's board on January 23, 2008.

Mr. Goldenberg asked for clarification regarding how security works in this system, and what percentage of products are included. He also asked how many computer systems they are integrating, given that California has many systems to deal with. Mr. Goldenberg also asked about motivation for these efforts, and if it began because the government pays for the drugs in Europe.

Mr. Noon stated that Aegate's system tracks products containing a large random number (serialized key) on the pack. The product is scanned and information goes back to the central database and the number tries to "find itself." The process takes only about one-third of one second. If a duplicate is identified, the first pharmacy where the product was sold is notified, as well as the pharmacy that has scanned the same number for the second time.

Mr. Noon referred to their pilot efforts in New York, and that they learned to embed the authentication process in the existing scanning process. He noted that scanners

reading more than one technology (2-D and RFID) ran too slow. He said he would share the data set from their work in New York with California's board.

A person from the audience asked whether the database is a web-based repository or if it's proprietary.

Mr. Noon responded that it is a high-level security database. He added that speed and security could only be ensured by putting it in one secure place.

Mr. Goldenberg asked whether Aegate is willing to do a pilot study in California.

Mr. Noon responded that he wants a task force to see if all players want to go in that direction first. Otherwise, it will be a waste of time.

PUBLIC COMMENTS

- **National Coalition of Pharmaceutical Distributors (NCPD)**

Gene Alley, Vice President of Regulatory Affairs, spoke on behalf of NCPD. He said their organization represents and supports independent drug wholesalers nationwide. NCPD members distribute to physicians, clinics, pharmacies, long-term care facilities, surgery centers, dentists, and government entities, and almost half of their members are VAWD (Verified Accredited Wholesale Distributor) certified.

Mr. Alley said that small distributors benefit end-users; for example, they can source products for hospitals that hospitals cannot get through their regular chains during an emergency.

Mr. Alley noted that NCPD members have been dealing with paper pedigree requirements for two years, and they can serve as a resource to the board regarding what has and has not worked in Florida. He said that NCPD supports measures that increase the security of the nation's pharmaceuticals, and urges California to involve all stakeholders in the pedigree implementation process.

Mr. Alley spoke about surety bonds, and said California's current requirements burden small distributors. NCPD suggests that one national surety bond (proportionate to revenue generated by sale Rx drugs) be permitted for all states nationwide.

Mr. Alley stated that though patient safety must be the primary concern, serialization is a big problem. Meeting the January 1, 2009 deadline will be challenging. Mr. Alley stated that pharmacies are dependent on manufacturers to determine which technology to buy. Therefore, a delay should be granted to pharmacies. He further stated that an electronic pedigree without serialization would be better than no pedigree for another two years in California.

Mr. Alley emphasized that NCPD supports a phased-in approach, implementing e-pedigree except for the bonding and serialization requirements. NCPD asks for a delay in serialization until 2011 and then only implement it on a risk-based approach for high-risk drugs. He asked that NCPD be included as one of the board's many resources to help determine the best method to protect consumers.

- **Stephanie Feldman Aleong**

Ms. Aleong introduced herself as a former statewide prosecutor in Florida. She planned and directed Operation Stone Cold, a pharmaceutical racketeering prosecution, which became the subject matter for the non-fiction book by Katherine Eban, Dangerous Doses.

Ms. Aleong said what happened in Florida was that lot level pedigree was a "sham" pedigree. In her experience, what you demand of the industry is what will be possible. She advised that people show the board why no delay in implementation is necessary, instead of arguing that a delay is necessary.

Ms. Aleong said the board has initiated a forum that also will encourage written comments from people who say don't delay. She is encouraged by California because Floridians listened to the fears instead of forcing industry to come forward with hard data. She said industry has been talking about this issue since 1987, and she urged the board not to delay implementation.

- **Siemens Corporation**

Jeff Schaengold, Traceability Internal Consultant, spoke on behalf of Siemens Energy & Automation, Inc. He also provided a written statement of his testimony to the board.

Mr. Schaengold noted that the cost to modify one packaging line has been overestimated when stating it will cost \$500,000. He said actual costs are lower, with higher costs usually incurred during pilot projects. The "cloning" of packaging lines brings the actual cost down quite a bit.

Mr. Schaengold recalled previous warnings that every company would be put out of business if they had to computerize. Later came warnings that every company would (again) be put out of business, this time because they had to put barcodes on their products. E-commerce was the latest thing that was going to put every company out of business. Despite the warnings, no traumatic events occurred. He emphasized that businesses adapt and conform, and he strongly recommended that California's e-pedigree implementation date not be delayed.

Mr. Schaengold said that Siemens supports patient safety, and that delaying e-pedigree implementation beyond January 1, 2009 would jeopardize that patient safety. He said

that traceability is 95 percent adoption of the principle and 5 percent deciding on standards. Delaying adoption of drug traceability is unjustified, considering that traceability and serialization have been used in the aviation, automotive, and electronics industries for the several decades.

Mr. Schaengold stated that the concept of serialization is not new or expensive, and serialization of a drug would cost a fraction of a cent per unit. Siemens is making their resources available to companies that need to fast-track their package serialization to meet California's deadline. They have worldwide resources ready and able to support any drug manufacturer in order to meet the January 1, 2009 implementation date. Siemens IT services and employees stand ready to improve the delivery of drugs, prevent counterfeit drugs from entering the marketplace, and prevent drug dispensing errors.

Mr. Schaengold said that Siemens is capable of marking, reading, and verifying products on a conveyor line faster and better than any other company in the world. In addition, Siemens will not provide grandfathering exceptions or waivers.

Mr. Schaengold gave an example of buying a \$25 printer from a Wal-Mart in Connecticut. When the clerk scanned the product UPC code, a screen-prompt directed the clerk to scan the serial number as well. If ink jet cartridges and printers can be serialized, why are oncology drugs not serialized? Mr. Schaengold urged that there be no delay of implementation for California drug pedigree.

2. Possible Use of Inference for Serialized Drug Products in the Supply Chain or Grandfathering of Unserialized Drug Products Already in the Supply Chain on January 1, 2009

Mr. Room stated that the way in which the board had hoped the discussion would proceed was that presenters would use the Implementation Submission Statement Template posted to the board's Web site. The template was developed to help industry communicate how they perceive grandfathering or inference would look within their system.

One template was submitted regarding inference from EPCglobal, and there were no submissions from industry. The board understands generally what inference is, but was interested in what inference means to industry, and how and when they would use it. Would they use inference at the front end or the back end of the supply chain?

Ms. Herold referred to EPCglobal's template submission on inference (attached to these minutes). Slide 4 included three serialized inference definitions as follows:

- **Infer:** Conclude from evidence (Webster's Dictionary).
- **Working definition:** To infer the serialized number, based on information provided by the upstream supply chain, reasonable inspection of the product,

and application of the Serialized Inference Rule by the Shipping and Receiving partners.

- **Serialized Inference Rule:** The process a supply chain partner uses to ensure there is enough evidence to infer the serialized number without physically reading ALL serialized numbers. A Serialized Inference Rule should be defined for each packaging unit (e.g., pallet, case, item, etc.) for the key process steps of Commission/Aggregation, Ship, and Receipt.

Mr. Celeste spoke on behalf of the EPCglobal's HLS Industry Adoption Task Force. He provided excerpts from a body of work containing general material on inference.

Mr. Celeste stated that California's Business and Professions Code Section 4034(b)(3) requires the name and address of each person certifying delivery or receipt. The business problem presented is that serial numbers, especially on a 2-D bar code tag, are not always visible and opening each case to certify individually tagged items would be time-consuming. 'Inference' is one suggested solution to this business problem.

Mr. Celeste said that serialized inference would assume that each trading partner is following good business practices such as:

- Good manufacturing and good distribution practices.
- Documented controls and Standard Operating Procedures.
- Uses quality metrics to minimize "defects" of inbound and outbound product.
- When process errors are detected, implements changes to those processes to prevent future errors.
- Processes are periodically reviewed for improvement opportunities.

Mr. Celeste summarized that serialized inference is possible when the following conditions have been achieved:

- A collection (item, full or mixed case, tote, pallet, etc.) is present.
- The collection is identified with a unique serial number, and each member of the collection (item, case, tote, pallet) is also identified with a unique serial number.
- The received trading partner receives an electronic communication containing the serialized numbers and the hierarchical relationship of those serialized numbers within the collection ("parent to child" relationship).
- The receiving trading partner must have assurance that the collection has remained intact since leaving the last trading partner.

Mr. Celeste noted that this information is intended to provide trading partners with an understanding of how inference can be used, but the application of inference remains an individual business decision.

Mr. Celeste also provided serialized inference scenarios including:

- Single Item Commission – apply serial number to one single item
- Item in Case Commission/Aggregation – apply serial number to case and build item-to-case hierarchy
- Case to Pallet Commission/Aggregation – apply serial number to a homogeneous pallet comprised of cases of all one product and build case-to-pallet hierarchy (may be a full pallet or a partial pallet)
- Tote or Mixed Case Commission/Aggregation – apply serial number to cases or tote containing either a mixture of SKU's or one or more items of a single SKU, and build item-to-case hierarchy (typically conducted as part of a pick/pack/ship operation)
- Mixed Pallet Commission/Aggregation – apply serial number to pallet of mixed cases or totes, and build case-to-pallet or tote-to-pallet hierarchy (pallet could contain mixed cases and/or full cases, and the full cases could be from one product or from multiple products)

Mr. Celeste acknowledged that inference is a risk because each item in an inference case is not specifically checked. He noted that inference is common in everyday life (a bottle of 100 tablets is purchased without verification that there is actually 100 tablets in the bottle).

- **DDN Pharmaceutical Logistics**

Bill Von Rohr spoke on behalf of DDN Pharmaceutical Logistics. Mr. Rohr stated that DDN represents 50 manufacturers. He said that per the regulations, pedigree must be authenticated when there is a change of ownership. For example, a manufacturer has a partner and that partner ships a pallet to that manufacturer; it will show the address of one partner and the name of the other. He asked whether they would need to authenticate the physical product against the record. He said as product moves down the supply chain, will they be told they're not authenticating enough, or just go back to manufacturer? What if they pull 50 cases off a pallet and compare that authentication to be the same as the physical products? Mr. Rohr suggested that for the agent of a person buying the goods, it would be a challenge to open every case to scan each unit.

Mr. Room responded that this is exactly the kind of data the board needs in writing in the template. The board does not know exactly how people will put this inference into practice and what kinds of problems they perceive.

Mr. Von Rohr said that he would be happy to write up the issue, and submit it to the board.

- **Walgreens**

Emily Stamos and another person from Walgreens commented on the issue of inference. They said inference is important because they see it as an interim step until

there is "no-line-of-sight" technology. In answer to the board's question about how inference would be used, Walgreens wants to use it in their distribution centers. Without inference, they will have to read every item to accommodate items where there is no line-of-sight. They would conduct "100 percent audits" initially for a particular manufacturer, then later read fewer items from the same manufacturer (or the three large wholesalers). They believe that ultimately a full read of everything could be done, but until that day comes, inference would allow them to use their good practices and make good business decisions, ensuring that people in California receive quality medications.

Mr. Room asked Walgreens to submit their comments in writing, including their trust with manufacturers, internal protocols, and ways to apply inference. He said that scenarios would be useful to the board. He added that inference is not risk free, and it cannot be hold-harmless.

Ms. Herold noted that it would be very helpful to know if a product is inferred all the way through to the pharmacy.

Ms. Stamos said that she would put together a visual presentation on the subject of inference, for the board's meeting on January 23, 2008. Regarding the subject of grandfathering, there is a challenge if they cut off orders waiting for tagged products. There would be empty spots on the shelves because certain products would not be ready at a certain time.

Ms. Stamos suggested that grandfathering be staggered. She gave an example of requiring manufacturers to grandfather until a certain date, then wholesalers would add six months to the original date, and so on, so that everyone can bleed out their inventory.

Mr. Room asked that these proposals be put in writing for the board.

Ms. Herold noted that the board would need to provide some enforcement discretion.

Ms. Stamos stated that some products have a long shelf life, and retail pharmacies may run the risk of destroying inventories, and it is costly to replace that inventory. For example, a product that is not due to expire before 2012 may be wasted.

Dr. Swart asked how much supply a pharmacy would have, for example, three months or a year.

Ms. Stamos responded that it's product specific. For example, they have some products that wouldn't expire until 2013. There is a wide spectrum as to how long product supply will last.

- **Safeway**

Ron Bingaman spoke on behalf of Safeway. Regarding grandfathering, Mr. Bingaman supported the comments made by the representatives of Walgreens. He also said that in retail pharmacies, inventory goes through at different rates. He said he would provide written comments to the board. He supports a tiered approach by category.

Mr. Bingaman also supported the use of inference with spot check oversight, until industry comes together and the system standardizes itself. After industry finalizes track and trace standards, they will put together a system, dependent on track and trace serialization being adopted. Assuming a product is serialized, whether it's 2-D barcode or RFID, they could have a working pilot going within 120 days.

- **Longs Drugs**

Jeff Beadle spoke on behalf of Longs Drugs. He said he supported Walgreens comments regarding a phased-in approach.

Mr. Beadle said that products become more suspect once they are out of the case. As a case moves downstream, it's been opened by multiple parties in the supply chain. By keeping a container in tact, you keep an additional barrier for an added layer of security.

Mr. Room noted that is what he meant by identifying which transactions may or may not be appropriate for inference. Products sold as whole cases all the way down to retailers would be an example.

- **Kaiser Permanente**

Steve Gray spoke on behalf of Kaiser Permanente. He said that pharmaceutical quality is based on inference. For example, they assume what's it says on the bottle is what is in the bottle.

Dr. Gray gave an example of an advance shipping notice of cases arriving by air or freight. Those kinds of shipments are inferred because containers are not opened.

Regarding grandfathering, Dr. Gray said enforcement discretion should be category specific. He gave an example of a drug for black widow spider venom that may not be dispensed to a pharmacy, but can be delivered in a couple hours. It is similar to medication for rattlesnake venom. Dr. Gray suggested that long-term grandfathering may be needed because some these products have only a few manufacturers and are manufactured very infrequently.

Mr. Room asked Dr. Gray to include these examples as part of a written submission.

Dr. Gray clarified that if patients needed a product, that product should be able to be brought in to the state during an emergency, and that there should be enforcement discretion. He asked the board to support that type of legislation. He also suggested that if there was a domestic supplier not in compliance, but they have a product we need, grandfathering would be in order.

ADJOURNMENT

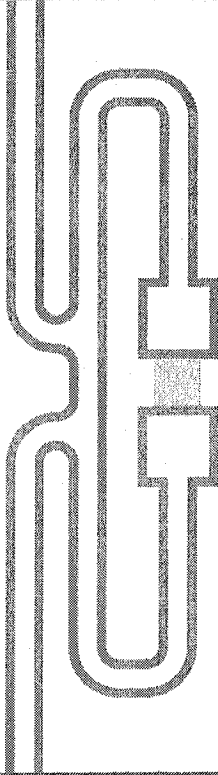
Mr. Goldenberg emphasized that the board has heard presentations on what industry cannot do, and wants to know what industry can do to ensure the safety of Californians.

Ms. Herold stated that a template would be developed for submissions regarding implementation of California's pedigree. The template will solicit comments requesting delay as well as requests not to delay implementation. It will be posted on the board's Web site.

There being no further business, Chairperson Goldenberg adjourned the meeting at 5:12 p.m.

**PRESENTATIONS TO E-PEDIGREE WORK GROUP
ON DECEMBER 5, 2007**

- Alien Technology
- California Pharmacists Association (CPhA)
- National Community Pharmacists Association (NCPA)
- Generic Pharmaceutical Organization (GPhA)
- Three Rivers Pharmaceuticals
- TEVA
- Watson Pharmaceuticals
- PhRMA
- California Health Care Institute (CHI)
- EPCglobal
- Aegate
- National Coalition of Pharmaceutical Distributors (NCPD)
- Siemens Corporation



Pharmaceutical e-Pedigree

UHF RFID Considerations

Victor Vega
Director, Technical Marketing
Alien Technology Corporation

5 December 2007



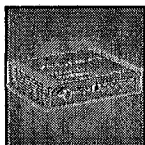
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CONTEXT



HURDLES / ADVANCEMENTS



DEMO / Q & A



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The UHF RFID industry has significantly advanced in the past few years, with substantially improved technology enhancements, healthy cost reductions, and a robust global UHF infrastructure.

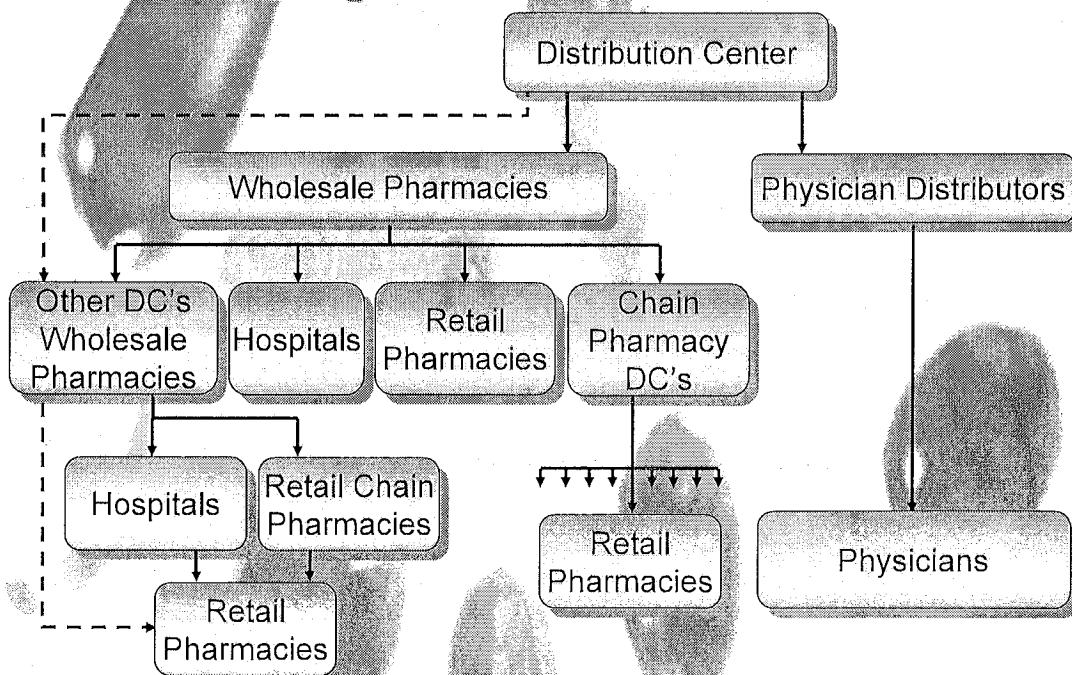
In this briefing, we take a look at a few of the previous hurdles, and the recent UHF technological industry advancements.



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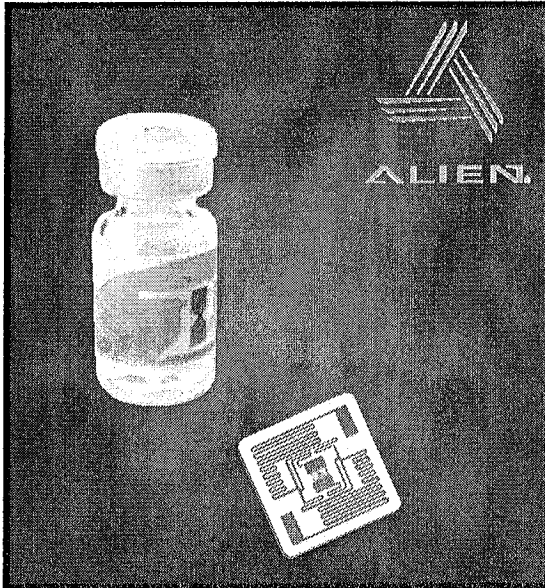


Pharmaceutical Pedigree Channel Management



Rev A

Pharmaceutical RFID Motivations



- Electronic Pedigree
- Patient Safety
- Counterfeiting
- Channel Diversion
- Inventory Management
 - Expiration / Out-of-Stocks
- FDA Endorsement
- Sample Management
- Containment
- Reverse Logistics
- Supply Chain Management
- Marketing
- >35 States considering e-pedigree legislation



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Public Information



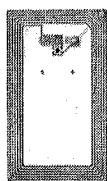
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e-Pedigree Options – Item / Case / Pallet

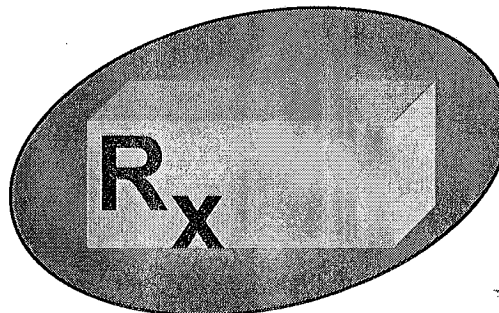
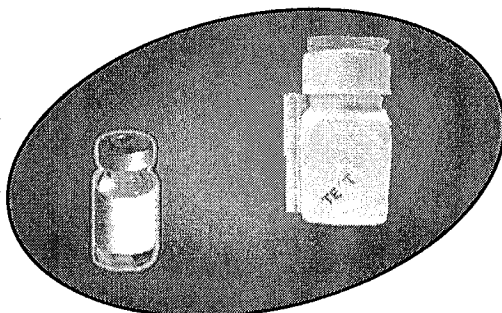
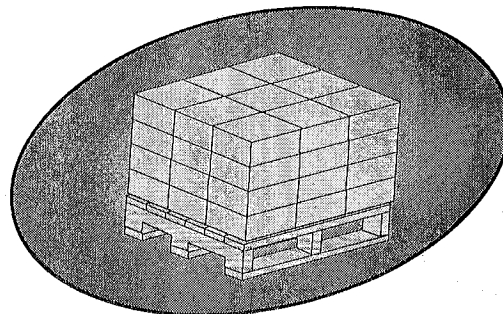
2-D
Data Matrix



HF
RFID



UHF
RFID



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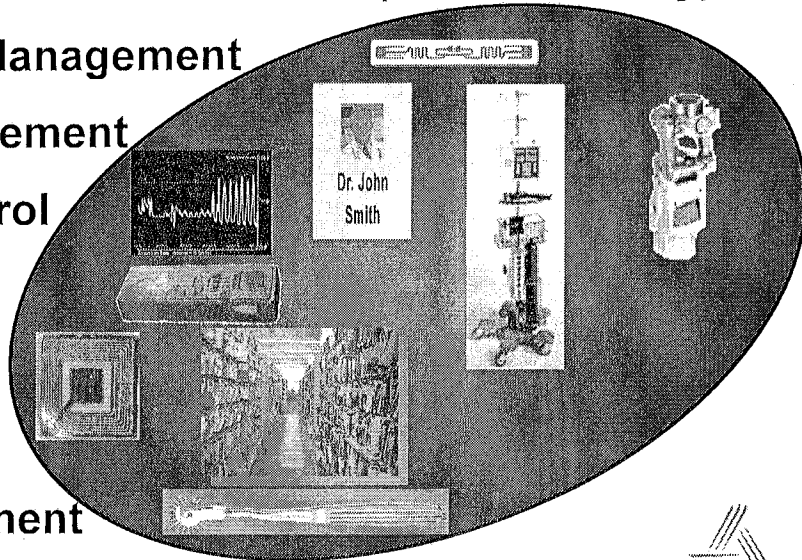
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Other Wireless Infrastructure Considerations

- Electronic Article Surveillance (EAS – security)
- Cold Chain Management
- Asset Management
- Access Control
- Dispense
- Surgical
- Prosthetics
- File Management



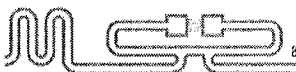
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RFID Considerations

TOPIC	DISCUSSION
RF Exposure	No notable EMI efficacy on Potency / Stability / Temperature of Biologics or pills
Challenges	Absorbent water-based content / gel-packs Limited item-level surface Small items and vial diameters Metal or foil surfaces Shadowing / Shading (close proximity of tags to one another)
Benefits	Electronic pedigree / Brand Protection Channel management Reverse logistics: Product recalls / containment Integrated born-on / expiration date code assists with first-in, first-out stock rotation. Optimize storage densities, enhance inventory management, minimize out-of-stocks Improved transportation and logistics management efficiencies
Applications	Item level vials / prescription bottles Case / bulk / pallet tracking Self dispense – (hospitals / medical offices) Cold chain temperature monitoring and recording Electronic manifest capability Smart shelf notification modes for changing inventory status
Cost	Consider cost of multi-faceted infrastructure & labor / error for line-of-site solutions



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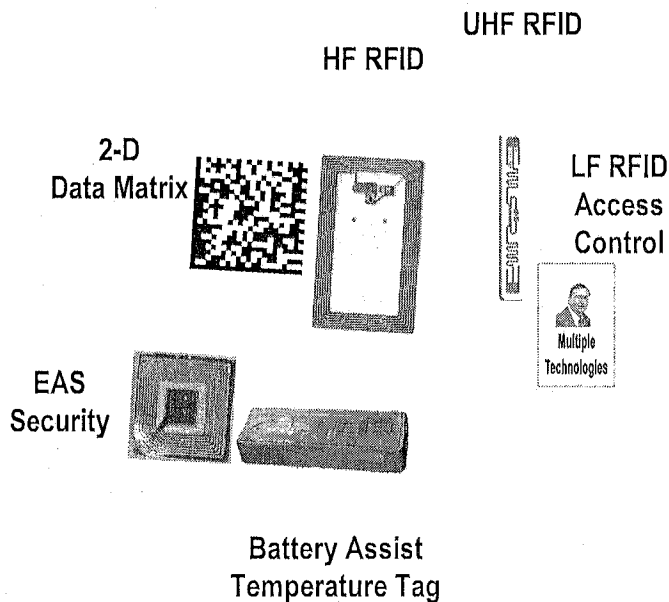
Spectral RF Considerations

FEATURE	13.56MHz Near Field Coupling (High Frequency, HF)	915MHz Far Field Coupling (Ultra High Frequency, UHF)
RF Efficacy	No known effects (e.g. on protein biologics / pills)	No known effects (e.g. on protein biologics / pills)
Advantages	<p>Free space read ranges typically < 1/3 meter</p> <p>Water based product does not significantly impede near-field magnetic coupling</p> <p>Mature product offerings</p> <p>Globally accepted frequency</p>	<p>Excellent free space read range, > 5-7 m</p> <p>Reduced read range of smaller tags on product often still exceeds optimum HF read range</p> <p>Simplistic, low cost tag antenna / construction</p> <p>Single UHF technology deployment simplifies technology / cost infrastructure</p> <p>Open protocol / several suppliers</p> <p>Fast read rates</p> <p>Global standard and frequency (860-960MHz)</p> <p>High adoption drives low pricing</p> <p>UHF offers both magnetic near field & electric far-field coupling.</p>
Disadvantages	<p>Not a viable long range solution (e.g. case/pallet)</p> <p>High-Q inductive resonant loops easily de-tuned</p> <p>Inductive bridge adds MFG complexity / cost</p> <p>Dual technology HF/UHF tag & reader (UHF likely for longer range, e.g. cases/pallets) will add to infrastructure cost (e.g. readers, antennas, tags, support, programmers, etc.)</p> <p>Typically higher relative pricing than UHF (e.g. 3x)</p>	<p>Absorptive water based products impede electric far-field performance, but performance often exceeds that of HF.</p>

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Multiple Technologies



UHF

UHF RFID

Items
Cases
Pallets
Security
File Management
Access Control
Vending



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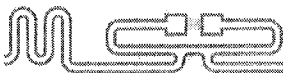
CONTEXT



HURDLES / ADVANCEMENTS



DEMO / Q & A



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Technology Hurdles of the Past

- ~~Tags challenged on material other than Free Space~~
- ~~“Dumb” Readers, Unable to Filter / Mask~~
- ~~Tag Size~~
- ~~Customized Tags per Product Category~~
- ~~Tag Prices~~
- ~~Regional Tag Design Requirements~~
- ~~Reader Collision~~
- ~~Severe Tag De Tuning on Product~~
- ~~Short Read Range~~
- ~~Wireless Access Point Contention~~
- ~~Sluggish responses~~
- ~~Limited Suppliers & Support~~
- ~~Severe Tag ESD Issues~~
- ~~Interference Susceptibility~~
- ~~Tag Shadowing / Shading~~
- ~~Unfriendly User Interfaces~~



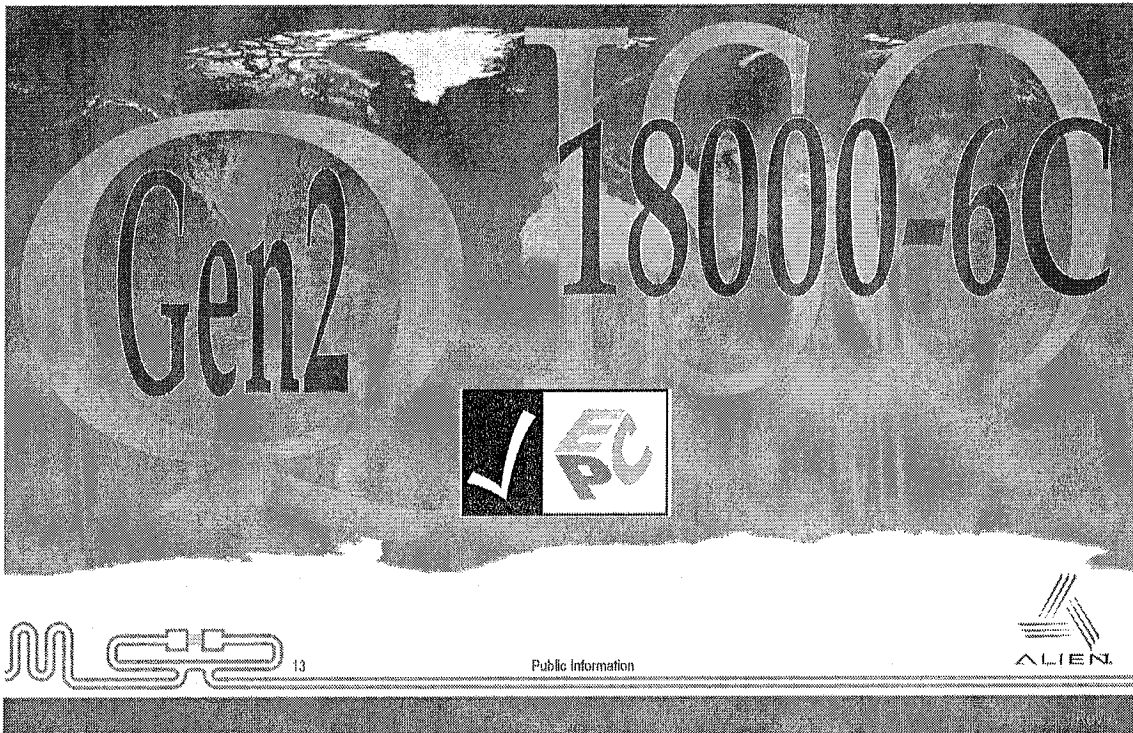
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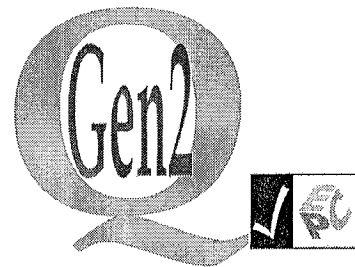
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Global Standards



Adoption Barriers – Is it the Hardware?

- Absolutely not
- Gen2 is globally accepted
- World Tags operate globally
- Gen2 is flexible & scaleable
- The technology is stable, robust & reliable
- 4th generation EPC hardware platforms
- 5th generation EPC Tag IC's
- Multiple IC, Tag, Reader, Antenna, software and system providers in the marketplace



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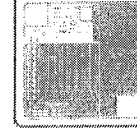


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Silicon Developments - Present

- **RFID Silicon**

- Superior sensitivity
- Extended user memory
- Enhanced noise rejection
- Vastly increased acquisition & programming speeds



- **Wide Spectral Bandwidth**

- Alleviate regional tag incompatibility
- Wide operational spectral band (860-960MHz)



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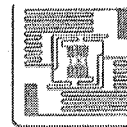


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UHF RFID Tag Developments

- **Performance / Characteristics**

- Global Tag Designs
- Small Item-Level UHF geometries (e.g. 0.9" square)
- Minimal tag detuning performance degradation
- "One-size-fits most" tag advancements
- "**Optimal**" free space read ranges > 10 meters observed (though not practical on product)
- E-field tag reads demonstrated on / in aqueous materials
- Near 100% tag yields



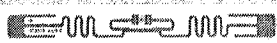

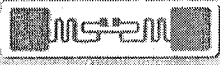
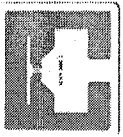

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Wide Tag Selection (many others available)

TAG	Highest Volume	Global Tag	General Purpose	Price Leader	Highest Performance	Small Item
	✓✓	✓✓	✓✓	✓✓	✓	
	✓	✓	✓	✓	✓✓	
	✓✓	✓✓	✓✓	✓✓	✓	
	✓	✓	✓			
	✓✓	✓				✓



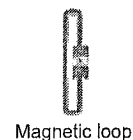
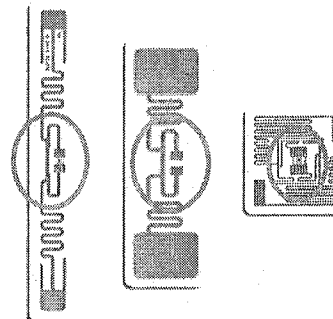
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UHF Tag Anatomies

- Some UHF RFID tag antennas accommodate both Near & Far fields.
- These tags (shown) are conventional Far-field dipoles - notice the loop in the center? This serves to couple the near-field component as well.
- A UHF RFID tag with a concentrated near-field (a.k.a. magnetic-field, or inductive-field, or H-field) might look like that shown to the right. Its read range would be very short relative to the dipoles.



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Tag Snapshot

Attribute	Past	Present
Typical approximate UHF form-factors	$\frac{3}{4}$ " x 6", 4" x 4"	0.9" x 0.9", $\frac{3}{4}$ " x 3", $\frac{1}{2}$ " x 4"
Memory	64 / 96 bit ePC	96 bit ePC + optional user memory (e.g. up to 512 bits)
Volume Inlet Prices	~ \$1	<10¢ typical
Applications	Pallets	Cases, Pallets, Assets
Typical Optimized Free Space Read Range	1.5 – 3 meters	10-30 meters



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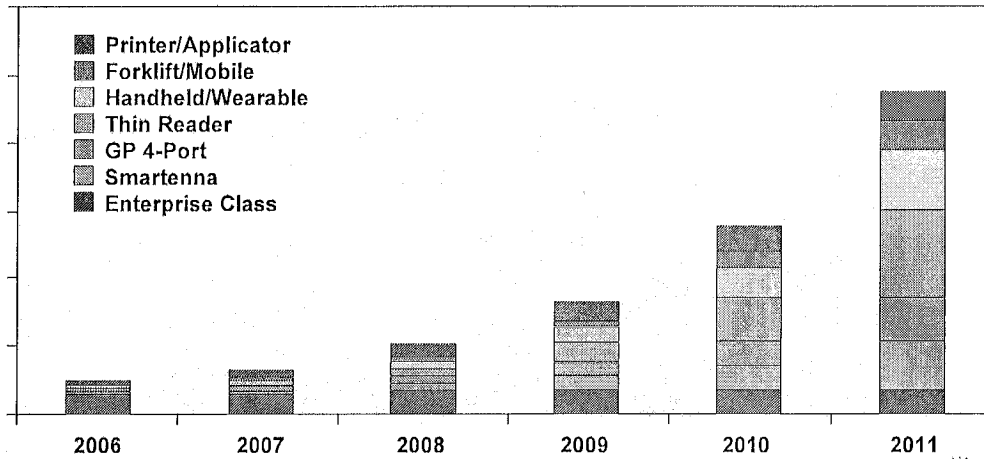
EPC Gen2 RFID Security Overview

FEATURE	CONVENTIONAL RFID (e.g. ePC Class 1 Gen2)
Authentication / Counterfeit	Moderate
Duplication	Moderate Difficult with Custom TID
Memory	ePC Class 1 Gen2: 96 user bits Optional user programmable memory (e.g. manufacturer, National Drug Code (NDC), S/N, born-on / expiration date, channel & ECC authentication)
Additional Security Options	Tamper-proof label Self destruct inlay Random Item ID's with "CRC Case Tag" Custom TID Security encode/decode Key (like Access Control) 32 bit Access P/W; 32 bit Lockable Memory PermaLock option

Rev A

Emerging Reader Diversity

Increasing application-specific reader embodiments



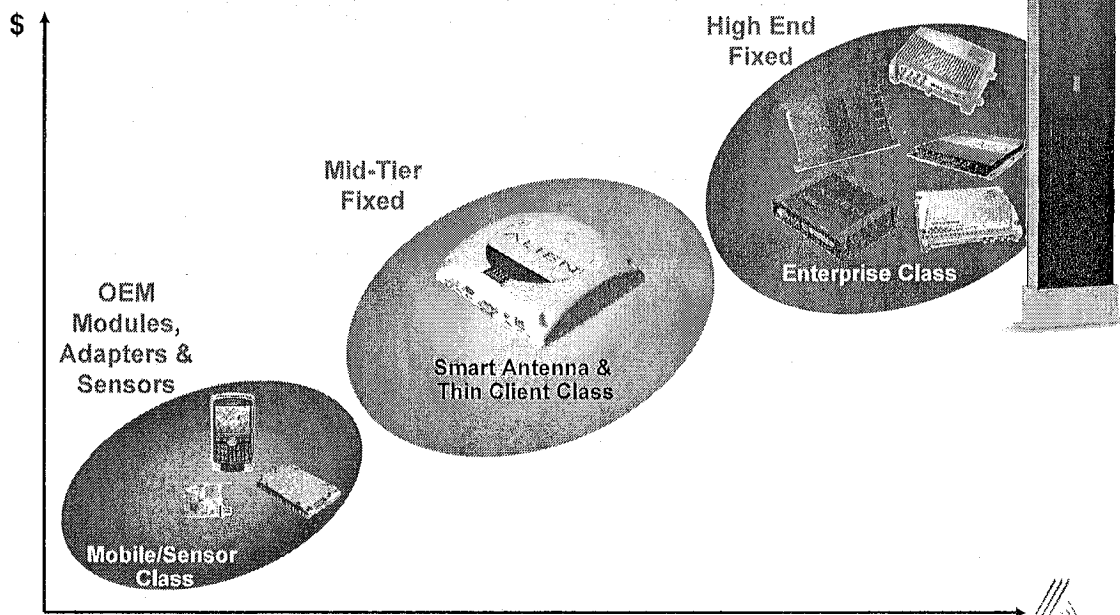
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Reader Diversification Trend



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Function



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Marquee Software Operating Environments

- Marquee software commitments promote strong industry stability & reinforce interoperability.

Microsoft

BizTalk RFID

IBM

WebSphere 6.0

ORACLE



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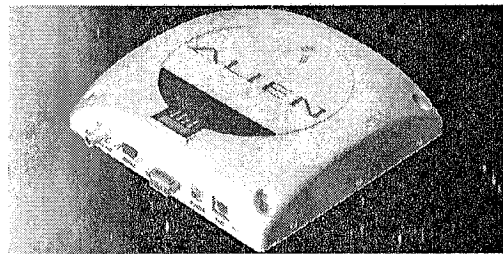
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Smart Antenna Class Attributes (ALR-9650)

- **Simple installation**
 - Small, low profile footprint
 - Power-Over-Ethernet
 - Combined Reader / Antenna
- **Scaleable**
 - Serial and LAN connectivity
 - Optional external antenna port
 - (2) Digital Inputs and (2) Digital Outputs
 - Remote firmware and version management



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High-Performance Enterprise Reader (ALR-9900)

- **High performance**

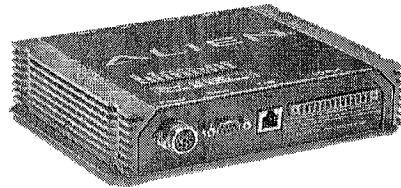
- Optimized for high read success with large tag populations
- Superior interference rejection in dense reader environments
- Interference mitigation ("sniff & read")

- **Easy to manage**

- Remote firmware, version, identification management
- SNMP, configurable UDP heartbeat for reader status
- Crisis recovery: LAN and power loss
- Triggered network upgrades

- **Easy to integrate**

- Small footprint (approx 8" x 8" x 2")
- Optically Isolated GP-I/O (4 In / 8 Out)
- Easily configurable Profile files
- Monostatic – Single antenna per read point



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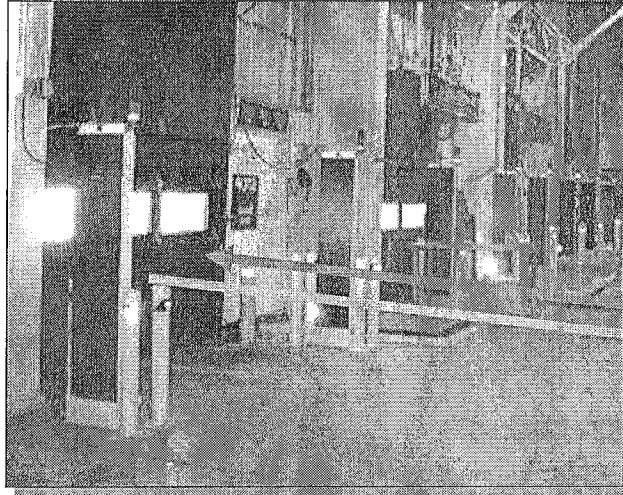
Reader Snapshot

Attribute	Past	Present
Volume Reader Prices	~\$3,500	~\$600 to \$1,500
Optimal Free Space Read Range	2 - 3 meters (1.5 – 2 m practical)	10-30 meters (5 – 7 m practical)
Interference rejection	Terrible. 0 Interferers.	Great. 4+ interferers.
System Infrastructure	Reader, Filtering Host, Heavy Middleware, Enterprise	Reader, Middleware, Enterprise
Primary Fixed Reader Vendors	Alien, AWID, Matrix, SamSys ThingMagic	Alien, Impinj, Symbol, ThingMagic, Sirit, Omron, Intermec, etc.
Stability / Reliability	Poor.	Great.

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Reader Enhancements

- Direction Detection



Outbound
Inbound



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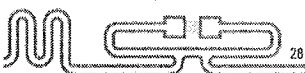
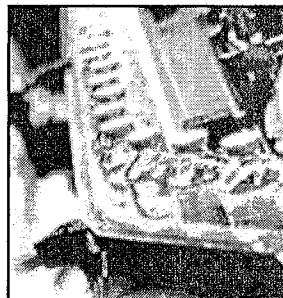
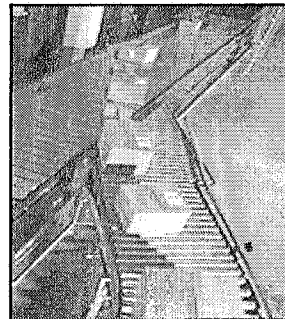
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REV A

Future Reader Expectations

- Singulation / Diversion



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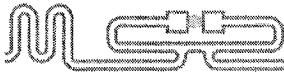
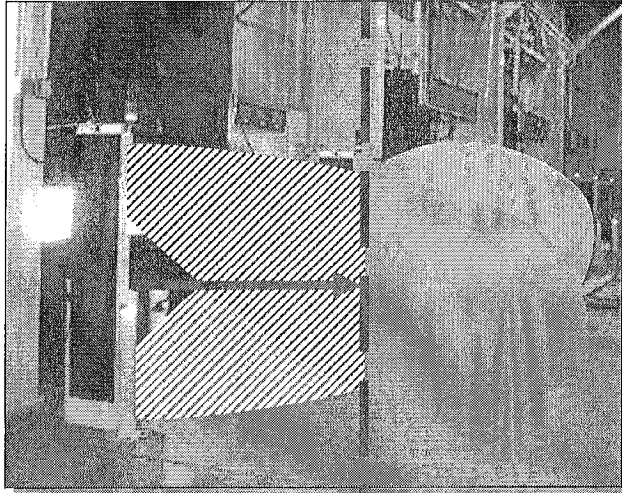


REV A

Future Reader Expectations

- Defined perimeter acquisition

- Without reducing read performance margins, only process tags within a defined perimeter.



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Public Information

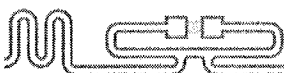


Rev A

**Remember – *you* (downstream partners)
are driving this industry**

Multiple Technologies

Simplicity



30

Public Information



Rev A



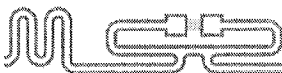
CONTEXT



HURDLES / ADVANCEMENTS



DEMO / Q & A



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Additional Info (posted for 2 weeks)

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COMPANY | PRODUCTS | INDUSTRY | APPLICATIONS | SERVICES | PARTNERS

Products

- RFID Readers
 - ALR-9900
 - ALR-9800
 - ALR-8800
 - ALR-9650
 - ALX-9010 Portal
- RFID Tags
- Services
- How to Buy

WHITEPAPER DOWNLOADS

Thank you for your request for more information.

- Click here to download the Common RFID Implementation Issues: 10 Considerations for Deployment Whitepaper.
- Click here to download the RFID and UHF: A Prescription for RFID Success in the Pharmaceutical Industry Whitepaper.
- Click here to download the IBM Solution for Pharmaceutical Track & Trace Whitepaper.

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Rev A

Common RFID Implementation Issues




Whitepaper
**Common RFID
Implementation Issues:**
10 Considerations for Deployment

Introduction

Early RFID implementations were fundamentally driven by external mandates, but along with significant technological improvements, more readily available component options, cost reductions, and shared lessons learned, the technology has proven its value in driving significant operational efficiencies, and RFID has gained a broader adoption.

Today, industries are looking beyond the realm of compliance, as they seek competitive advantages and integrate RFID much earlier into their production processes. Innovative companies are expanding the use of RFID in their supply chain, logistics and asset tracking operations. As a result, they are achieving demonstrable improvements in supply chain visibility, forecast accuracy, reduced out-of-stock situations and reduced counterfeiting.






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Public Information



RFID and UHF: A Prescription for RFID Success in the Pharmaceutical Industry

**RFID and UHF:
A Prescription
for RFID Success
in the
Pharmaceutical
Industry**







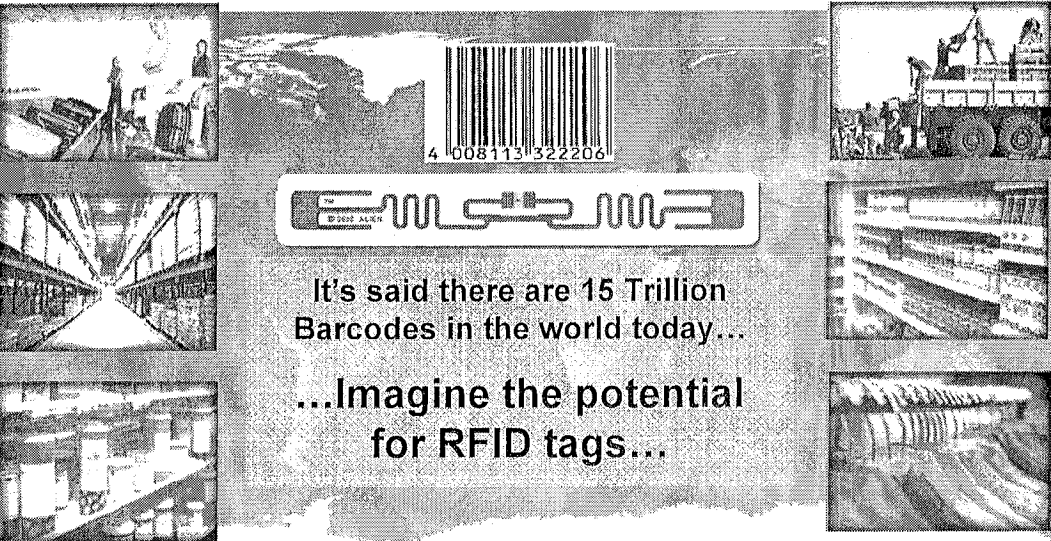
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Public Information



Rev A

Food for Thought



4 008113 522206

It's said there are 15 Trillion Barcodes in the world today...

...Imagine the potential for RFID tags...



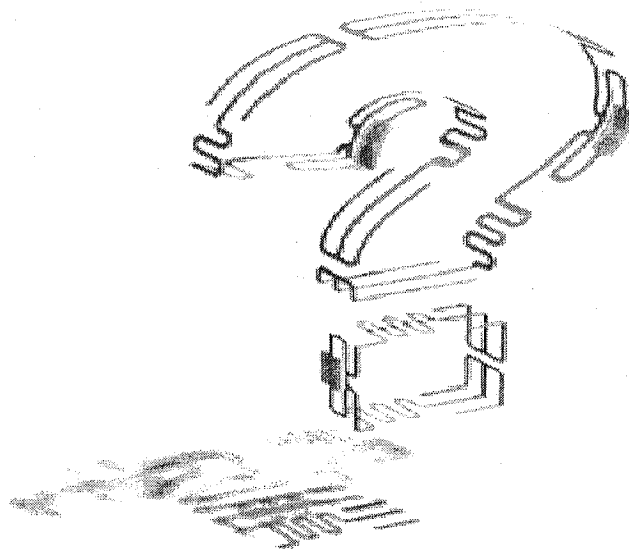
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Questions?

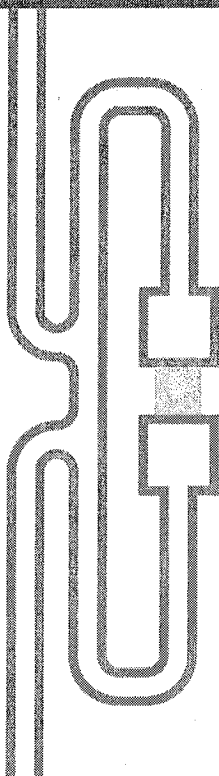


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Public Information



Rev A



For more information:

Victor Vega

email: vvega@alientechnology.com

Website: www.alientechnology.com

White Papers (posted for 2 weeks)
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Thank You!



California Pharmacists Association

Presentation for Enforcement Committee
Work Group on E-Pedigree Meeting
December 5, 2007

Kathleen Lynch, Esq.
Vice President of Government Affairs



California Pharmacists Association

- Our Members
- Their Mission
 - Integral part of the Health Care Team
 - Solution driven
 - Patient Advocates



Issues with E-Pedigree Legislation

- **Timing**
 - Equipment
 - Space
 - Budget
 - Training Personnel
 - Upstream Partners
- **Cost**
 - Estimates from various groups
- **Technology**
 - Interoperable



3

Issues with E-Pedigree Legislation

- **Inference**
 - Definition
- **“Grandfathering”**
 - Stock in hand on 1/1/09
 - Product received from upstream partners after 1/1/09 without pedigree
- **Enforcement**
 - Reliance on upstream partners
 - Last minute decisions



4

Pharmacists Working Towards Compliance

- Education on E-Pedigree
- Meetings with Wholesalers
- Participating in Pilot Programs

5



2008 Issues Facing Pharmacy

1. Implementation of Average Manufacturer Price (AMP)
2. E-Pedigree Implementation
3. Tamper Resistant Prescription Pads Requirement
4. Development of New Labeling Requirements
5. Possible Increase in Payroll taxes due to Health Care Reform
6. Drug Disposal Programs
7. Medicare Part D

6



**Written Testimony of David Wilcox on behalf of the
National Community Pharmacists Association before the
Enforcement Committee of the California Board of Pharmacy
Hearing on E-pedigree
December 5, 2007
Sacramento, California**

I. Introduction

Members of the Enforcement Committee (the Committee), on behalf of the National Community Pharmacists Association, I thank you for this opportunity to testify on E-pedigree issues.

NCPA represents the nation's independent pharmacists, including the owners of more than 23,000 pharmacies, with 75,000 pharmacists, over 300,000 employees and millions of patients who rely on us for their prescription care. In California we represent 2,215 independent pharmacies and their over 30,000 employees.

Many NCPA members are California pharmacists like me. I live in Fresno and am currently the president of PharmKee, Inc., a group of 10 pharmacies serving rural areas including Colinga, Caruthers, Easton, Lodi, Madera, San Joaquin, Mendota, Kerman and Fresno. I have been a practicing pharmacist since 1979 and am active in my community with the Chamber of Commerce, Planning Commission and the California Pharmacists Association, of which I am a former president. Serving rural patients is the primary focus of our pharmacies. We further specialize in serving the health care needs of low-income families.

II. The January 1, 2009 Implementation Deadline Should be Extended to January 1, 2011

We support the need for a safe drug chain of custody. NCPA wants to work with the Committee and the California Board of Pharmacy (Board) to facilitate a smooth transition to the new system. However, in order for independent pharmacists to obtain and maintain the E-pedigree technology, there must be a mechanism of financial support for community pharmacy to offset the monetary costs associated with implementation of an interoperable electronic system.

As you know, we are the end of the line in the drug chain of custody and are concerned that the lack of interoperability will force pharmacists to purchase multiple track and trace technologies – readers, scanners, etc. – with associated upgrades and to spend time training staff to understand and use the equipment and systems. It will also be necessary to spend considerable administrative time in our pharmacies managing any track and trace functions. None of these activities are being financed by the state. The state has, in effect, handed community pharmacy an “unfunded mandate!” At the end of the day, NCPA believes the public good is best served by implementing E-pedigree only when there is a complete, interoperable electronic system that can truly prevent, in an economical fashion, counterfeit drugs from entering the system.

B. The E-pedigree technology is not ready -- and the public good is best served by delaying implementation

NCPA is unaware of any vendor that has the technology ready to be purchased and operated at an affordable price. More importantly, there is no evidence that the existing technology is universally interoperable. Since the California law requires that E-pedigree shall be "created and maintained in an interoperable electronic system, ensuring compatibility throughout all states of distribution" *Section 4034(a)* and certain companies are not prepared to implement E-pedigree, then by definition, there is no single, interoperable system. Therefore, anyone who tries to move or sell prescription drugs would then be in violation of the law. *Sections 4034(c), 4263(c), 4263(d), 4034(i)*.

NCPA has advocated for a single, federal, standardized and interoperable system of pedigree, serialization and electronic track and trace technology at the retail level that requires only one set of equipment to facilitate. We believe that the California law largely mandates interoperability, but it can be argued that it does not explicitly mandate a single interoperable technology. The pharmaceutical industry appears to be proceeding with the understanding that multiple technologies and devices are in compliance with the law. We are concerned that enforcing the current deadline would cause too many implementation problems as a result of this situation.

The statutory matter before the Board is whether, and if so, in what manner, to extend the implementation date. Ideally, NCPA believes that the pharmacy would be the end recipient of the chain of E-pedigree custody and that E-pedigree requirements are best designed to be implemented up to the wholesaler level. We recognize, however, the state of California law and advocate two approaches that will help to successfully implement E-pedigree issues:

1) NCPA advocates a phased-in approach to meet an extended implementation date, which places priority on high-risk drugs that are most susceptible to counterfeiting and diversion. While NCPA acknowledges that phased-in implementation may not be an ideal solution, it appears that a phased-in approach is necessary. The Board must decide whether phased-in implementation would begin before or after January 1, 2011.

2) Whenever implementation begins, the requirements should become binding at the retail pharmacy level after it is mandated upstream. Additional implementation time of one year or more will help address the magnitude of the logistical, administrative, financial and quality of care issues of requiring implementation of the new technology at the retail pharmacy level.

C. The Cost to Pharmacy should be recognized and addressed in the implementation process.

As E-pedigree is implemented, independent pharmacists should be compensated for the costs associated with the purchase of multiple technologies. The costs to a retail pharmacy to comply with E-pedigree requirements are estimated to be anywhere between \$10,000 to \$40,000. These costs include obtaining the hardware, software and staff training necessary to administer, monitor and maintain the system as required by law. *Section 4169(5)*.

The above-stated estimate is consistent with implementation estimates that were presented by retail pharmacies to the California Board of Pharmacy at its September meeting: Chain pharmacies have estimated initial per store implementation costs at \$25,000 - \$35,000 with an additional \$5,000 - \$6,000/year. One chain pharmacy stated that even once the plans of upstream trading partners are known, an additional 15 - 18 months would be necessary to implement E-pedigree. Another chain pharmacy projected that it would take \$54 million for one distribution center covering 591 pharmacies to achieve end-to-end serialization. They, too, are hindered by the lack of preparation by upstream manufacturers. Another chain pharmacy concluded that its pharmacies cannot support multiple technologies and systems considering the scope of trading partners involved, nor can they deploy multiple technologies at each location to ensure connectivity with each trading partner. For those of us in the independent pharmacy sector the consequences are even worse because we are small businesses and do not have the resources of a national chain pharmacy.

I understand that the Committee and Board would like to receive detailed projections and analyses. We know that the Board would like to have active industry involvement in evaluating costs, such as through participation in pilot studies. To the degree that independents are able to participate in such studies, NCPA would be glad to facilitate such participation.

What concerns me, however, is the apparent acceptance of Walgreen's September statement that it is preparing a "very big catcher's mitt" to catch the variety of serialization approaches that it expects to receive. Walgreens stated their intent to adapt to the variety of serialization technologies that various manufacturers may choose to use. Independents simply cannot adapt to the variety of pedigree, serialization and track and trace technology that will be used under the current status of preparedness for implementation.

NCPA believes that it will not be in the best interest of public safety to proceed with implementation when it has been demonstrated that the undeveloped nature of the technologies falls far short of the interoperability as required by California law to be achieved in time to ensure compliance with the January 1, 2009 date. The Board has the authority to mandate an extension of the deadline, but the Board cannot by fiat say there is compliance with the law if E-pedigree is implemented without true interoperability. Not only is it good public policy to extend the implementation date, but requiring universal E-pedigree to begin without ensuring interoperability runs counter to the California law.

In 2006, the first year of implementation of the Medicare prescription drug program, 1,152 independent pharmacies in the United States were closed or sold to other companies. After five years of stability in the independent sector, we witnessed this five percent decrease in community pharmacies in just one year. The costs associated with implementing E-pedigree will be too high for some California pharmacists to absorb. This means even more small business pharmacies will be put in jeopardy. This will harm patient access to prescription drugs and consultation care.

D. Recent Federal Law is Another Reason to For the Board to Proceed Prudently to Ensure Government Mandates do not Run Ahead of Universal Standards and Technological Developments

To review, the pedigree language passed by Congress this past fall included provisions that require the FDA Secretary to develop a standardized numerical identifier "(which, to the extent

practicable, shall be harmonized with international consensus standards for such an identifier) to be applied to a prescription drug at the point of manufacturing and repackaging . . . at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug.” *P.L. 110-085, Sec. 913*. The Secretary must do so by late March, 2010 (30 months after enactment).

In order to avoid the very real possibility of implementing a California standard only to face a different federal standard, it would be helpful for the Board to extend the implementation deadline to the date authorized by Section 4163.5 -- January 1, 2011. Choosing the extension does not mean that pedigree preparation should or will come to a halt. Instead, the interagency collaboration and industry consultation as mandated by the federal law will give affected parties an opportunity to work together to create a uniform system of pedigree within the confines of both the federal and California laws. NCPA would appreciate strong support by the Board for the interest of independent pharmacies and their patients in the state and federal process.

The need for careful work to harmonize the federal and California law is highlighted by the federal law highlighting RFID as a promising technology¹, even though the FDA has historically not been receptive to RFID technology. It is unknown how the Secretary will react to the most recent discussions about track and trace technology in California. E-pedigree and track and trace technologies are not a well-developed field either in terms of technological or commercial acceptance. NCPA believes there is a definite benefit to extend the deadline to allow the pharmaceutical community better opportunity to plan likely federal developments before California E-pedigree is implemented.

III. Inference

There does not appear to be a universal definition of inference. NCPA takes inference to mean that a transported container has a label that identifies the items within, but the recipient is not required to physically identify that each contained item matches up with the list of items. The recipient of the container is, however, allowed or required to “infer” that the container contains the listed items.

The California law requires that E-pedigree tracks each dangerous drug at the smallest package or immediate container distributed and received and that there must be a unique identification number established at the point of manufacture that is uniformly used.² Allowing for inference appears to be a concession that “smallest package serialization” is not obtainable. Where unit level serialization is not possible and inference is instead needed, NCPA does not believe that the recipient of the container — including pharmacists — should be required to receive the container and accept any liability that might arise from accepting a container whose packing list does not match the products contained therein.

¹ *P.L. 110-085, Sec. 913, amending Chapter V of the Federal Food, Drug, and Cosmetic Act at new 21 U.S.C. 505D(b)(3)*.

² “A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler and relieved by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug.” *Section 4034(d)*.

“...uses a unique identification number, established at the point of manufacture... that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.” *Section 4034(i)*.

NCPA questions whether true safety is adequately protected by inference. However, if the Board sees the need to have inference then a pharmacist and other recipients of “inferred” containers should be held harmless for the contents of the container.

IV. Grandfathering

NCPA supports a clean and easy to remember “grandfathering” rule – permitting non pedigree drugs manufactured before the final implementation deadline to be moved and sold up to one year after the implementation date. At that time, pharmacies should have at least a six month window in which to return any non-pedigree product to wholesalers, distributors or manufacturers for credit.

V. Conclusion

NCPA appreciates this opportunity to discuss the national interests of independent pharmacy in California E-pedigree issues. Extending the implementation date is just one step in the E-pedigree process, and NCPA looks forward to continued dialogue with the Board on these issues.

Because of the inability at this point to achieve interoperability, the costs involved, the effect on independent pharmacies and the potential for confusion and harm to patients/consumers, NCPA requests this Committee to recommend to the Board that it exercise its discretionary powers pursuant to Section 4163.5 to extend the implementation date to January 1, 2011, with additional time for pharmacy compliance.

NCPA also has the following requests:

- 1) that the Board only implement inference with a pharmacy hold-harmless provision
- 2) that “grandfathered” non-pedigree drugs may be distributed up to one year after the implementation date followed by six or more months in which to return any pre-pedigree products for credit

Generic Pharmaceutical Association (GPhA)

California Board of Pharmacy
Enforcement Committee Meeting

December 5, 2007

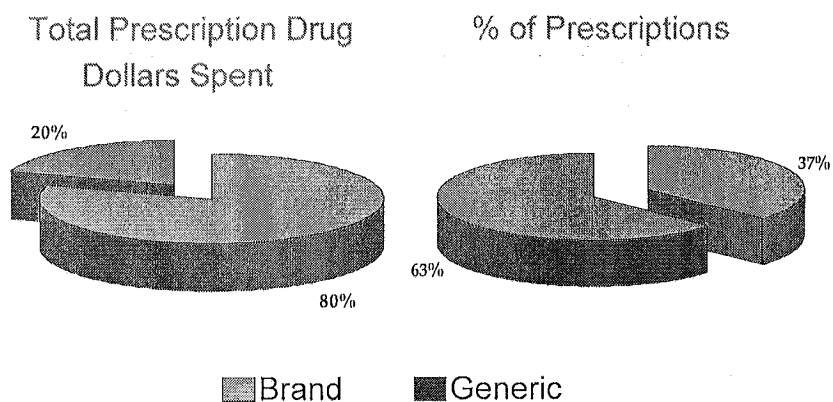
Presentation Outline

- Generic industry overview
- Anti-Counterfeit policy
- Current efforts toward compliance
- Potential impact for generic manufacturers
- Challenges to unit level serialization
- Electronic Pedigree Solution
- Summary
- Conclusions

GPhA Overview

- GPhA's members manufacture over 90% of the generic medicines dispensed in the U.S.
- Generic medicines comprise 63% of all prescriptions dispensed in the U.S., yet account for only 20% of the pharmaceutical expenditures
- Cost to consumers is 30%-80% less than the brand
- 1% decrease in generic drug utilization = \$4 billion in additional healthcare costs

GPhA Overview



GPhA Position on Drug Counterfeiting

- Consumer access to safe, effective and affordable generics remains GPhA's top priority
- GPhA recognizes that introduction of counterfeit products into the U.S. supply chain would pose a serious threat to public health
- The U.S. supply chain is currently the most secure in the world
- WHO estimates that the world's drug supply is 10% counterfeit; but the U.S. drug supply is 1% counterfeit or less—FDA credits supply chain vigilance
- Support appropriate and effective measures to make the supply chain even more secure

GPhA Position on Drug Counterfeiting

- GPhA is committed to maintaining and improving the security of the drug supply chain.
 - Due to their low cost, generic drugs are not likely targets for counterfeiters
 - GPhA has requested data from FDA on instances of counterfeit generic medicine
 - To the best of GPhA's knowledge, current anti-counterfeiting measures have resulted in no instances of counterfeit *U.S. generic* medicines occurring in the normal chain of distribution in at least the past 5 years

Current Efforts to Comply with CA Pedigree Law

- A survey of GPhA members indicated that:
 - GPhA members have conducted internal cost analyses of electronic pedigree and/or serialization
 - Large and some medium sized generic manufacturers have completed or are currently in the process of conducting pilot studies
 - GPhA's economist:
 - Henry J. Kahwaty, Ph.D., Director, LECG, LLC
1725 Eye Street, N.W., Suite 800
(202) 446-4422

The Generic Industry Is Working to Implement Serialization

Steps taken to date include:

- Selecting and implementing solutions for e-pedigrees
- Supplying Wal-Mart with package-level serialized products for a subset of SKUs
- Soliciting proposals for packaging line and other hardware modifications, middleware, and internal or external data centers
- Developing pilots with contract manufacturers, distributors, and large retailers
- Conducting studies of optimal placement for RFID tags and determining the best RFID tags available for specific applications
- Working with vendors to convert existing serialization systems and data structures from lot-level to item-level serialization
- Working with consultants to determine best approaches to supplying serialized products

Serialization Start-up Costs

- We estimate that the start-up costs for the equipment needed to modify packaging lines will cost generic producers over \$500 million
 - Cost includes only those for adding capital goods to the assembly lines (scanners, etc.)
 - Data management costs alone would exceed this amount
- There are additional start-up costs as well
 - Acquiring servers to house and process data
 - Developing or licensing middleware
 - Adjustments to shipping areas of manufacturing plants and distribution centers
 - Testing new lines, including procuring any regulatory inspections and approvals needed
 - Reviewing and modifying operating procedures
 - Packaging line downtime for construction and testing

Serialization Operating Costs

- Item-level serialization adds costs to the production of individual packages
- Serialized labels will be more expensive than those currently in use
 - Labels including RFID technology will cost between \$0.25 and \$0.30 more than the labels currently in use
 - Labels with pre-printed 2D barcodes will cost between \$0.02 and \$0.03 more than the labels currently in use
 - There are additional operating costs as well. For example, outsourcing data management can cost \$0.10 or more per item
- We estimate that generic producers' operating costs will be over \$300 million annually just for RFID-enabled labels

Potential Impact of Unit Level Serialization on Generics

- Unique business model:
 - Competitive commodity market; narrow profit margins on products
 - Higher volume and broader range of products than brand manufacturers
 - Regulatory variables influencing the generic market create uncertainty in timing of product launches
 - Whatever affects the generic market will have direct repercussions on public health and access to affordable medicine in California and throughout the U.S.

Potential Impact of Unit Level Serialization on Generics

- Effects on Competitiveness
 - Manufacturers unable to meet compliance by 1/1/09 will be out of business in CA this reducing the competition that results in lower generic prices
 - Participating companies will be at a competitive disadvantage in the other 49 states, unless products bound for CA could be segregated in the supply chain—not practically feasible
 - Less competition due to fewer competitors, or fewer competing products could result in higher prices

Potential Impact of Unit Level Serialization on Generics

- Several wholesalers have informed manufacturers that they expect products to be pedigreed and serialized by June or July of 2008
- Manufacturers will have to begin production of serialized products AT LEAST by May of 2008
- GPhA favors 'grandfathering' of products entering the supply chain prior to the January 1, 2009 deadline

Potential Impact of Unit Level Serialization on Generics

- Potential effects of unit level serialization on access:
 - Cost of achieving compliance will significantly increase the production cost of generic medicine
 - Large scale withdrawal from the market of low-cost/low-margin products is possible
 - Interruption of packaging lines for validation in a short period of time could result in disruptions of supply chain and/or shortages of medicine in California and throughout the U.S.

Note: Case or pallet level serialization would be less likely to result in problems, interruptions or shortages

Potential Impact of Unit Level Serialization on Generics

- Effectiveness as Anti-Counterfeiting Measure:
 - GPhA believes that the benefits, feasibility and effectiveness of large scale unit serialization of all products is unproven and requires further investigation
 - Allowing time for pilot studies to progress and less expensive options to be explored could be more beneficial to public health

Challenges to Serialization

- A major impediment has been cost of implementation in conjunction with a lack of agreement among stakeholders on one technological standard that will support interoperability
 - Taking on the cost of experimentation is not an option for many generic manufacturers, especially small and medium sized manufacturers
- Ongoing operational costs of serialization are based on units sold; generic medicines sell at a much lower cost and higher volume than brand; thus generic companies have much lower available price margins

Challenges to Serialization

- Major impediments to implementation and to early adoption:
 - No guidance for implementation of track and trace
 - Currently, no agreement on EPCIS usage
 - Lack of industry agreement on standards for serialization
 - The capability of software vendors to implement systems for the entire supply chain by 1/1/09 is doubtful
 - Inability of the industry to even discuss use of single technology due to federal anti-trust laws
 - Difficulty in validating databases to manage necessary information by 1/1/09
 - Patient/consumer privacy concerns
 - Lack of technical expertise broadly within the industry to implement and manage the IT infrastructure
 - Can tag vendors meet product volume demand?

Electronic Pedigree As Initial Patient Safety Measure

- Would stimulate development of infrastructure necessary to enhance track and trace capabilities
- Establish a more reliable method for authenticating shipments of product
 - Product is associated with an electronic pedigree and each change in ownership may be validated
- Would enable lot location, facilitate recalls, and enhance expiry management
- Manufacturers envision this step as feasible by the January 1, 2009 deadline

Summary

- The benefit of access to low cost generic medicine is at risk as high implementation and operational costs will raise production costs
- Challenges of implementation could reduce competition—fewer competitors and fewer competing products
- Disruptions in the supply chain may impact public health and patient safety
- Increase public sector healthcare costs

Conclusions

- GPhA encourages an industry wide review of weak points in the supply chain that allow counterfeit medicines to enter, so that strategies may most efficiently address such vulnerabilities
- GPhA will continue to work with the Board of Pharmacy and other stakeholders to implement California's electronic pedigree laws in a manner that effectively and efficiently achieves our shared objective of securing patient safety and strengthening the integrity of the supply chain

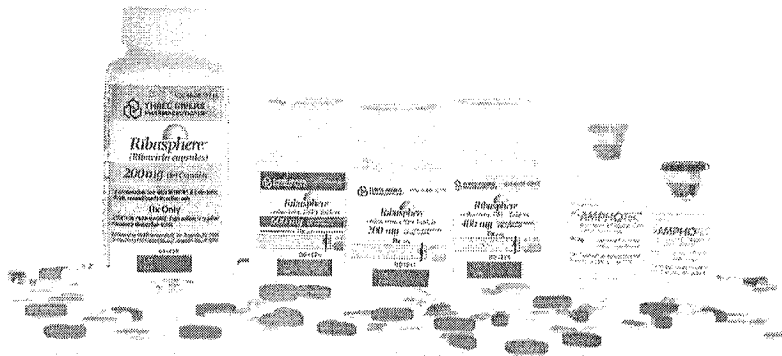
Request for Extension

- GPhA believes that industry cannot implement unit level serialization widely by 2009; additional time would allow:
 - Determination of feasibility of unit level serialization
 - Industry to ensure that standards are adequate
 - Determination of impact of costs to consumers and the healthcare system
 - Supply chain stakeholders to work towards a single, nationally acceptable system
- On behalf of the generic pharmaceutical industry, GPhA respectfully requests an extension of the deadline for implementation of California's drug pedigree requirements



**THREE RIVERS
PHARMACEUTICALS®**

Three Rivers Pharmaceuticals



Agenda

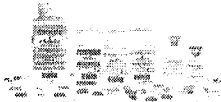
- Introduction to Three Rivers Pharmaceuticals
- ePedigree Readiness Strategy
- California Business
- Challenges
- Summary



**THREE RIVERS
PHARMACEUTICALS®**

Three Rivers Pharmaceuticals - Introduction

- » Founded in April 2000
- » Started with 3 Employees - Currently 40 Employees
- » Corporate Headquarters – Cranberry Township, PA
 - » Sales/Customer Service
 - » Accounting/Finance
 - » Quality and Regulatory
 - » Worldwide Distribution to over 41 countries
 - » Operations/Information Technology
 - » Legal/Human Resources
- » Contract
 - » Manufacturing/Analytical/Packaging




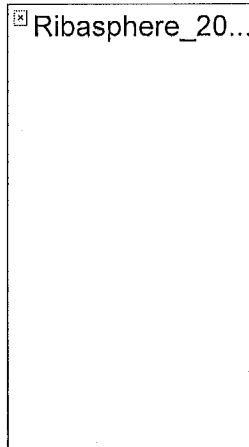
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Three Rivers Pharmaceuticals – FDA Approved Products

Ribasphere™ Capsules 200mg

For Combination Use with Peg-Intron
(peg-interferon alfa-2b, recombinant)
injection for the treatment of chronic
hepatitis C in patients 18 years of age
and older with compensated liver
disease previously untreated with
alpha interferon or who have relapsed
following alpha interferon therapy.

 Ribasphere_20...



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Three Rivers Pharmaceuticals – FDA Approved Products

Ribasphere™ Tablets 200mg, 400mg, 600mg

For Combination Use with
peginterferon alfa-2a for the
treatment of adults with chronic
hepatitis C virus infection who
have compensated liver
disease and have not been
previously treated with
interferon alpha.

☒ Ribasphere_tab_family

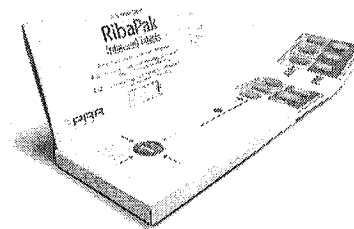


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Three Rivers Pharmaceuticals – FDA Approved Products

Ribasphere Tablets RibaPak™

For Combination Use with
peginterferon alfa-2a for the
treatment of adults with chronic
hepatitis C virus infection who
have compensated liver
disease and have not been
previously treated with
interferon alpha.



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Three Rivers Pharmaceuticals – FDA Approved Products

Amphotec®/Amphocil®

50mg/100mg

Amphotericin B Cholesteryl Sulfate Complex
for Injection

- Sterile, Lyophilized Powder for Reconstitution and IV Administration
- For the treatment of invasive aspergillosis.



 **THREE RIVERS
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Pedigree Readiness Strategy

- Understand requirements and monitor the development of standards
- Work collaboratively with vendors, customers, and trading partners
- Develop standard, cost-effective solution
- Work closely with packaging vendors and software solution providers
- Integration with current validated distribution system (under 21 CFR Part 11 – Electronic Records and Signatures)



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EPCIS and Implementation – EPC Global© 2007

- How might a sample implementation work for a small company?
 1. Determine how to capture and share EPCIS business events
 2. For data capture, setup EPC readers and middleware
 3. For data sharing, make arrangements with trading partners to monitor shipments and receipts of EPC-tagged products
 4. Compile master data for the products and locations in the supply chain
 5. Setup an EPCIS data repository application with help of solution provider
 6. Load master data into the repository
 7. Route captured EPCIS events from its middleware to its EPCIS repository via the capture interface
 8. Setup subscription queries with trading partners to track shipments
 9. Enable use cases by building applications on the base EPCIS infrastructure



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State of California

- Significant volume of specialty pharmacies
- State of California business
- Institutional business serviced through wholesalers
- State requirements will likely become national standard



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Challenges

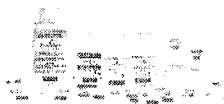
- ePedigree initiatives will consume 100% or more of 2008 I/T Budget
- Contract vendors in FDA filing may take different approaches
- Individual compliance requirements by state and customer/trading partner



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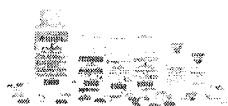
Summary

- Concern about understanding requirements
- Item-level serialization – Vendor cooperation
- Find solution which meets requirements and ensures supply chain efficiencies
- Deploy an architecture to allow for long term growth
- Patient safety and security of supply chain is a priority for 3RP



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Thank You





Securing the Pharmaceutical Supply Chain:

A Generic Manufacturer's Perspective

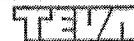


California Enforcement Committee

December 5, 2007

Opening Remarks

- TEVA supports the goal of securing the integrity of the pharmaceutical supply chain to ensure the provision of safe prescription drug products to the public
- TEVA is the leading generic pharmaceutical company in the world with the largest pipeline in the industry
- For the US market, TEVA ranks #1 of all manufacturers in TRxs filled
 - TEVA USA sells and distributes:
 - Over 1200 SKUs
 - Approximately 1 million saleable units of Rx drugs per day
 - Approximately 30 billion doses per year

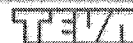


Supply and Distribution Chain

- 16 TEVA manufacturing sites supporting the US market
 - 8 US sites
 - 8 international sites
 - 68 unique internal packaging lines
- 50 outsourced manufacturers
- 5 contract packagers
- 1 primary US distribution site
- Hundreds of ship-to points



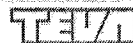
TEVA's success depends on the prompt, seamless coordination of a very complex supply and distribution network



3

Current Efforts to Promote Safety

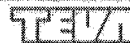
- Comply with existing federal and state-level pedigree laws
 - Require ADRs to purchase TEVA-labeled product either directly from TEVA or from another TEVA ADR
 - Pass ePedigree in other states where required
- Conform with FDA standards/cGMP requirements for drug manufacturers
 - Validate all manufacturing-related processes
 - Audit vendors of active and inactive ingredients as well as suppliers of outsourced finished product
- Participate through GPhA to promote effective federal and state laws to ensure supply chain integrity and seek standardization of related technology
- Established a corporate-wide anti-counterfeiting team to evaluate implementation of overt and covert identification technology into product and product packaging



4

Challenges of Item-Level Serialization

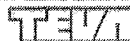
- Lack of unified standards for Track and Trace interoperability
 - Risk of adopting technology that may not prevail
 - Open questions regarding ability to rely on unit/case/pallet inference
- Long Implementation Timeline
 - Identification of workable equipment and technology
 - Need to conduct pilot studies along the supply chain
 - Validation of equipment and databases
- Disruption to Ongoing Operations
 - Packaging lines will need to be shut down to retrofit
- Significantly more expensive than lot-level ePedigree



5

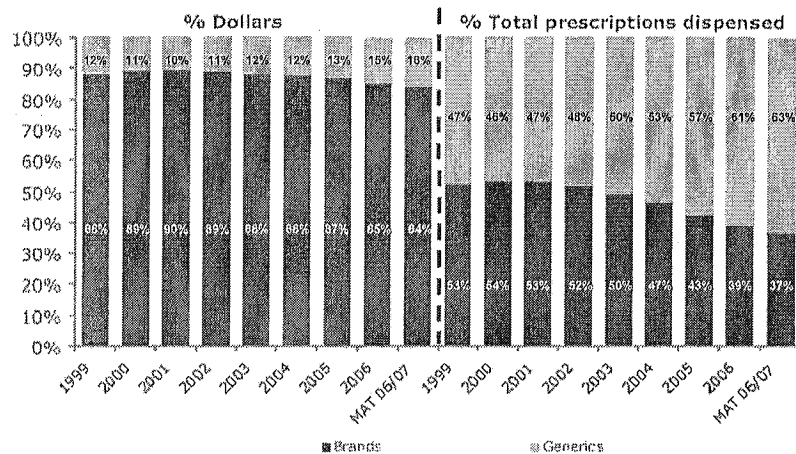
Impact on Generic Manufacturers

- The primary mission of the generic drug industry is to provide patients with high-quality, low-cost pharmaceuticals that are safe and efficacious
- The growth of generic drug utilization has saved the US public billions of dollars and has enabled some patients to receive treatment they otherwise may not have been able to afford
- The implementation of item-level serialization and track-and trace-capability will significantly increase the production cost of generic medicine
- Compared to their brand counterparts, generic manufacturers have lower revenues and profits and are therefore less capable of absorbing such costs—as a result, generic manufacturers may be forced to increase prices or even discontinue certain product lines



6

Generics v. Brands



Source: IMS Health, National Prescription Audit Plus, National Sales Perspectives, Jun 2007



TEVA

7

Actions to Date

- Formation of a global, interdisciplinary project management team specifically focused on compliance with CA pedigree
 - Ongoing evaluation of solution vendor proposals
 - Upgrading ePedigree capabilities to accommodate serialization
 - Planning Pilots with trading partners in each segment:
 - Wholesaler
 - Chain Drug Store
 - Third Party Manufacturer
 - Private Labeler
 - Re-Packager



TEVA

8

Implementation Timeline

- TEVA is currently formulating an implementation timeline
- Factors impacting timeline:
 - Multiple, different customer requirements
 - Equipment availability
 - Equipment validation
 - Potential labeling changes
 - Outsourced suppliers' ability to implement



TEVA

9

Estimated Implementation Costs

- \$35 Million estimated cost to install equipment capable of serialization (2D) on packaging lines only; not including incremental labeling costs or costs associated with distribution centers
- Tens of millions of dollars in additional operating costs per year
- Each implementation is unique and complex:
 - Varying line speeds
 - Non-standardized equipment
 - Available footprint / line space



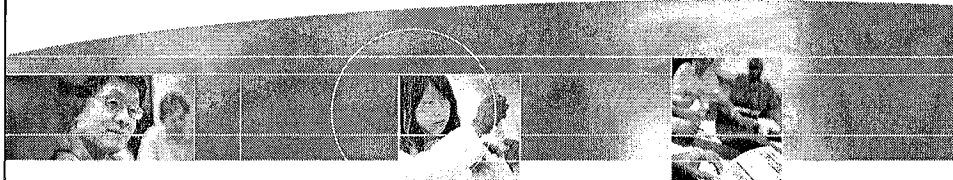
TEVA

10

In Conclusion

- TEVA supports a multi-faceted, risk-based and phased-in approach involving business practices, legislation/regulation, enforcement and technology to address issues that impact patient safety
- TEVA requests that the Board postpone as soon as possible the implementation date of the California Pedigree Law to:
 - Ensure continued supply of the full breadth of generic pharmaceuticals to the citizens of California
 - Enable the pharmaceutical industry to take the time needed to adopt a practical system at a reasonable cost





California Board of Pharmacy Enforcement Committee Meeting

Mary Woods
Exec. Director Call Center Operations
December 5, 2007
E-Pedigree

Agenda

- Background-Corporate Profile
- E-Pedigree Actions to Date
- Challenges
- Impact
- Next Steps
- Summary



2

Commitment to Patient Safety

Watson's Vision is inspired by our commitment to improve the health and quality of people's lives worldwide, we are fully dedicated to being a leading provider of pharmaceutical products.

As a testament to that statement our allegiance is to continually improve our practices to ensure a safe and secure product supply chain. Patient safety programs are always at the forefront of our business.



Watson At A Glance: Corporate Profile

Watson is a leading specialty pharmaceutical company that generated \$1.98 Billion in revenues in 2006 in three distinct business segments, Generics, Brand, and Distribution

Background

Established in 1984

3rd largest supplier of generic pharmaceutical products in the US.

**5th largest pharmaceutical company in US in total RX's dispensed.

Product Lines

Over 150 product families

Over 500 RX SKU's

Shipped 59MM RX selling units in 2006

**229MM RX's Dispensed 2006

Locations

13 Sites in US

Coleraine, Northern Ireland

Goa & Mumbai, India

Shanghai & Changzhou, China

** Source IMS Data 2006



E-Pedigree Actions to Date

- Support of all customer requirements to meet prior states pedigree requirements.
- Vendor and E-Pedigree application selection
- Long term serialization strategy
- Actively involved in industry and regulator task force
- 2 year RFID pilot with a Watson customer
 - Modified 1 packaging line
 - UHF Gen1 & Gen2 RFID pre-serialized labels
 - Scanners, Readers, licenses
 - Significant commitment and investment to investigative technology



Challenges

- Standards still being developed
- Interoperable technology guidance between manufacturers and different COT's.
- Outsourced manufactured product considerations
- Timeline constraints for manufacturing equipment installation, testing, and validation



Impact

Manufacturing

- Product supply considerations during equipment installation and validation
 - 6 mfg. sites, 32 packaging lines, shipping areas
 - Site specific evaluation based on product packaging
 - 500+ sku's
 - Approx. 60MM units
 - 2 Distribution centers
 - Approx. capital expenses \$15-20MM

Patient

- Cost impact to patient population



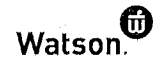
Next Steps

- E-Pedigree application implementation, trading partner testing, & deployment
- Long term serialization strategy prioritizing determined high risk products, and interoperable technology methods.
- Would consider on-going projects/pilots with selected wholesalers/distributors/chains to test interoperable technology
- Continue to participate as active members on industry councils and with regulators to solidify working standards for healthcare industry, and provide a safe and secure supply chain.



Summary

- Watson is committed to patient safety and enforcement of a safe and secure supply chain.
- Watson will continue to move forward in our efforts to meet California E-Pedigree requirements.
- Watson will continue to participate in efforts with selected customers for testing of interoperable solutions.
- Watson requests consideration for an extended implementation date by the CA BOP to ensure standards are in place, and to protect the integrity of the supply chain while continuing to provide lower cost alternative pharmaceutical products to Patients.



December 5, 2007

Efforts Underway To Enhance Supply Chain Security— Electronic Pedigree Offers Near-Term Patient Safety Benefits

Overview

- PhRMA fully supports public policy objectives to further strengthen the U.S. pharmaceutical supply chain and to help ensure patient safety, which lies at the heart of PhRMA companies' discovery and manufacturing of medicines.
- Any legislative or regulatory requirements to authenticate products and pass pedigree information should be uniform, should apply to all parties in the pharmaceutical supply chain, and should recognize the recent federal requirement for a standardized numerical identifier. Supply chain security is the responsibility of all parties involved in the distribution of products to American patients.
- PhRMA believes there is no technological "silver bullet" to protect against counterfeits. PhRMA member companies currently employ and routinely enhance a variety of anti-counterfeiting technologies, including covert and overt features on the packaging of high-risk prescription drugs. They have also adopted a range of business processes to better secure the supply chain and help facilitate the early detection of criminal counterfeiting activity. These are additional tools in the "tool box" to help strengthen the security of the pharmaceutical supply chain.
- Electronic pedigree is a viable near-term solution to help enhance patient safety and to provide additional supply chain security, while the necessary development, testing, certification and implementation work is being completed to support risk-based serialization.
- PhRMA supports mandatory use of electronic pedigree by all parties in the pharmaceutical supply chain, initiated by the manufacturer at the first commercial sale.
- PhRMA supports item-level serialization of products at high risk for counterfeiting, using a phased approach.
- PhRMA supports strong penalties for counterfeiters, including increased criminal penalties of 20 years' imprisonment, to help deter counterfeit activity.

Electronic Pedigree Should be Required for All Products as a Near-Term Solution

- Electronic pedigrees, available now, combined with lot-level information identification, provide a near-term solution to further secure the pharmaceutical supply chain and help enhance patient safety. Manufacturer-initiated electronic pedigrees could be implemented for all products at the lot level by the end of 2009.
- Manufacturers already use lot-level tracking for a number of functions, including product recalls, to help ensure patient safety. Lot-level tracking is one component of the Food and Drug Administration's (FDA's) current Good Manufacturing Practice (cGMP) requirements. By making this information available to downstream trading partners via electronic pedigree, the benefits of lot-level serialization could be used throughout the pharmaceutical supply chain.

- The FDA's cGMPs also require reconciliation of products. Reconciling product by the number of units received of a given lot number against product sold would assist the ability of trading partners to detect counterfeit items.
- Electronic pedigree with lot-level serialization provides an additional measure of security to the prescription drug supply, and would work in tandem with other overt and covert anti-counterfeiting technologies already employed by manufacturers. The entire supply chain would be accountable for documenting the source and chain of ownership for all products distributed. This would help close gaps that counterfeiters try to exploit to introduce counterfeit products into the legitimate supply chain. In addition, electronic pedigree, without serialization, has and will continue to help facilitate investigation and prosecution of counterfeit cases, and thus may have a deterrent effect.
- The FDA supports the use of electronic pedigree, and thus, PhRMA's position is aligned with the Agency's.
- The use of electronic pedigree at the lot level complies with the statement of intent of the California legislature in section 4163.1 that: "manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer's specific relationship in the distribution of dangerous drugs with wholesalers," pending technological feasibility of serialization.

Many Steps are Required Before Item-Level Serialization Can Begin; Technology Limitations and Other Challenges Directly Affect the Pace of Implementation

- While lot level serialization exists today – as required by FDA's cGMPs – the extension of this serialization effort to the case, or even the unit level, requires a myriad of activities by all supply chain partners. This collaborative effort to determine a viable technology standard has been adopted as part of the Food and Drug Administration Amendments Act of 2007 (FDAAA), and should be followed by future state legislative requirements.
- The implementation of unique identification beyond lot level will require significant changes to current manufacturing processes and facilities, many of which will require the development of guidance and/or pre-approval from FDA. Changes to manufacturers' labels and packaging may also require prior FDA approval.
- Significant data ownership and access issues must be resolved prior to item-level serialization, including relating to data exchange between supply chain partners, processes for verification of serial numbers, and issues related to commissioning and decommissioning a serial number.
- Processes to ensure the integrity of any track and trace technology will also be necessary.
- All of these activities – as well as the development and ratification of open standards which is described in more detail below -- must occur before any broad implementation may begin. The multiple steps required to implement serialization for all products or even a subset of products cannot realistically be completed by January 2009.
- The deployment of interoperable systems across the entire supply chain is a required prerequisite to implementation of the California pedigree law and is necessary to support the passing of pedigree and serialization information. The industry as a whole has significant work yet to complete before interoperability is possible.
- The implementation of electronic pedigree should not be delayed until these challenges have been resolved.

The Development of Open Standards is Necessary Before Item-Level Serialization Can Begin

- Serialization requires that open standards be developed and adopted in a number of areas, in addition to the activities described above.
- Specific standards that must be developed, include, but may not be limited to: RFID high-frequency item level serialization, serial number format for RFID, discovery configuration and installation, and discovery services. These standards must also address complex issues surrounding data integrity, interoperability, and compatibility across the supply chain.
- The standards described above have not been developed and/or ratified, and will not likely be available until mid-2008 -- at the very earliest -- and possibly as late as 2009.
- Once these standards are finalized, vendors marketing technology solutions will need to be certified to those standards and products built to conform to these standards. These steps must be completed before item-level serialization can begin, beyond planned pilot activities.

Recent Federal Legislation Directs FDA to Develop a Standardized Numerical Identifier by 2010; Any State Requirements Should Not Take Effect Until This Federal Process is Completed

- The recently-enacted FDA Amendments Act of 2007 (FDAAA) directs FDA to develop -- no later than March 27, 2010 -- a standardized numerical identifier to be applied "at the package or pallet level" to prescription drug products. In developing this identifier, FDA must consult with supply chain stakeholders and other relevant federal agencies and consider a variety of technological options.
- The terms "package" or "pallet" are undefined in the legislation, and thus, may not necessarily be read as automatically requiring that the standardized numerical identifier be applied to individual units of certain prescription drug products.
- The FDA is still considering the scope of its mandate under these provisions and developing a process to gain input from stakeholders and implement these requirements.
- The proliferation of differing state and federal requirements in this area would create confusion and could potentially negatively impact the pharmaceutical supply chain; therefore, one uniform, national standard is necessary.
- We recommend that California work with FDA as it develops a standardized numerical identifier, and consider delaying implementation of its state requirements to ensure that conflicting requirements do not result.


Product Level Serialization Should be Phased-in for Certain "High Risk" Products; Risk-Based Approach Will Facilitate Supply Chain Security

- A viable solution would be to begin with electronic pedigree at the lot level for all products and then phased in serialization at the case or item level for products most at risk for counterfeiting or diversion. Time and resources should be focused on those products whose counterfeiting would present the greatest safety risks to patients, such as life-saving medicines, or medicines most attractive to counterfeiters.
- The use of electronic pedigree at the lot level ensures that all drug products undergo security screening throughout the distribution channel, and phasing in serialization at the item level for those products identified at high-risk adds an additional layer of security.

- Any risk-based serialization approach should allow for the use of flexible technologies (e.g., 2D bar code or RFID) because certain medicines may not be amenable to particular technologies for package serialization, such as biologics.
- The FDA has recognized the value of a risk-based approach that focuses manufacturers and downstream partners on medicines at greatest risk of being counterfeited. Criteria has been developed by FDA to assist companies in identifying prescription drugs at high risk of being counterfeited, in order to support this risk based, phased-in approach to serialization.

Conclusion

- PhRMA fully supports public policy objectives to further strengthen the U.S. pharmaceutical supply chain and to help ensure patient safety.
- PhRMA supports one uniform standard for the authentication of products and the passing of pedigree information.
- PhRMA supports the use of electronic pedigree without serialization as a viable near-term solution to help enhance patient safety and to provide additional supply chain security. PhRMA supports the mandatory use of electronic pedigree by all parties in the pharmaceutical supply chain.
- PhRMA supports item-level serialization of certain products at high risk for counterfeiting, using a phased approach.
- PhRMA supports the use of interoperable systems throughout the supply chain to support the passing of pedigree and any serialization information.
- PhRMA looks forward to continuing to work with the California Board of Pharmacy and other supply chain stakeholders but is concerned that all steps required to achieve interoperability may not be reached by January 2009.



Member Survey Results

California Board of Pharmacy
December 5, 2007

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AND INNOVATION
www.chi.org

Slide 1

CHI
CALIFORNIA HEALTHCARE
INSTITUTE




California Healthcare Institute

- CHI is a statewide organization representing the state's life sciences industry.
- More than 250 of the state's premier life sciences companies—biotechnology, medical device, diagnostics and pharmaceutical companies, as well as the state's leading universities and private research institutions.
- Mission – To advocate for policies that promote medical innovation, access to the best medicines and therapies, and the health and well being of patients.

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Membership

- Member Organizations
 - 40% biotechnology
 - 26% service providers
 - 14% medical device/diagnostics
 - 13% pharmaceutical
 - 6% Academic and Private Research Institutions
- Innovators
 - 42% have one or more products on the market
 - 46% of those with products have revenues of less than \$100 million and fewer than 500 employees
 - Products range from inhaled and infused biologics, injectables, vaccines, implantable medical devices, diagnostic equipment and traditional chemical pills

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Survey Outline

- Conducted a survey of our members in conjunction with the Biotechnology Industry Organization (BIO).
- Purpose – To get a picture of what our members are doing to implement the e-pedigree law and an understanding of the challenges and issues they face in doing so.

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Respondent Profiles

- **Products on the market**
 - 17% more than 25; 33% between 10-25; 11% between five-10; 39% fewer than five
- **Manufacturing facilities**
 - 5% more than seven; 47% between four and seven; 32% between one and three; and 16% do not manufacture their own products
- **Packaging lines**
 - 5% have more than 20; 42% between 10-20; 37% between one-10; 16% have no packaging lines
- **Distribution centers**
 - 5% have four; 16% have three; 42% have two; 32% have one; and 5% have no distribution centers
- **Third party partners/contract manufacturers/other logistics providers**
 - 16% more than six; 56% between 4-6; 28% between one and three

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Serialization Implementation Status

Commercial Implementation of All Products
5%

Commercial Implementation of Limited Products
5%

Planning Phase
71%


Haven't Begun Planning
5%

Not Applicable
— 14%

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Planning Phase

- Testing various technology applications internally
- Pilots with other members of the supply chain
 - 36% expect to pilot in 3-6 months
 - 29% expect to pilot in 6-12 months
 - 29% expect to pilot in 1-2 years
 - 7% expect to pilot in 2+ years

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Challenges

- Technology concerns
- Production concerns
- Third party concerns
- Cost concerns

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Technology Issues

- Adopting an appropriate technology platform
 - No consensus among supply chain members (RFID vs. 2-D barcode)
 - Significant timing issues to meet implementation date
 - Infrastructure issues--data storage and ownership issues
- RFID
 - Use has not been validated with biologic products
 - Read-rates with downstream partners.
- 2-D Barcode
 - Throughput issues for receiving
 - Read-rates with downstream partners.

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Production Issues

- Lack of surplus packaging capacity required to ensure a continuous supply of product while the packaging lines are being reconfigured for unit level serialization.
- Good Manufacturing Practices (GMP)—Consequences if FDA approval is required for changes to packaging lines.
- Developing and implementing a serialization system is complex and expensive, requiring the installation and validation of new software and equipment.
- Accelerated stability testing will be required to ensure that the application of RFID tags to individual units does not affect a biologic medicine's integrity, physical characteristics or efficacy.

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Third Party Business Partner Issues

- Majority of our members rely on third party manufacturers, packagers, labelers and carton suppliers to get their products into distribution.
- Concern about our business partners' ability to comply.
- Even if our business partners can become compliant, our smaller members are extremely concerned about their needs being met.

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Third Party Solution Provider Issues

- Uncertain if technology providers have technology in place that is reliable and interoperable throughout the supply chain.
- Even if there are viable technology solutions, our smaller members are extremely concerned about their needs being met.

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AND PROTECTION

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Cost Issues

- More of an issue for smaller companies.
- Product serialization at each step of the drug distribution chain will require significant upfront and ongoing costs.
- Must dedicate significant human resources to compliance, a not insubstantial burden for many of our smaller companies.
- Must be sensitive to the ultimate concern about adding costs to the healthcare system as a whole.

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Summary

- 10% of our respondents believe they can be prepared to implement serialization across all or some of their product lines.
- The vast majority are in the planning phase.
- Our members support the law's goal of product integrity and patient safety.

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EPCglobal Update

State of Pedigree and EPC/RFID Standards

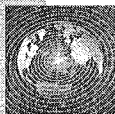
California Board of Pharmacy

December 5, 2007

Mike Rose, Tri-Chair, EPCglobal HLS IAG

Ron Bone, Tri-Chair, EPCglobal HLS IAG

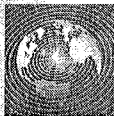
Bob Celeste, EPCglobal North America



Overview



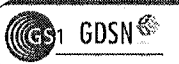

- State of the Standards
- Focus on Pedigree/EPCIS Assessment






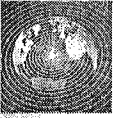
The Global Language of Business

OVERALL BENEFITS:
Improving efficiency & visibility in supply and demand chains

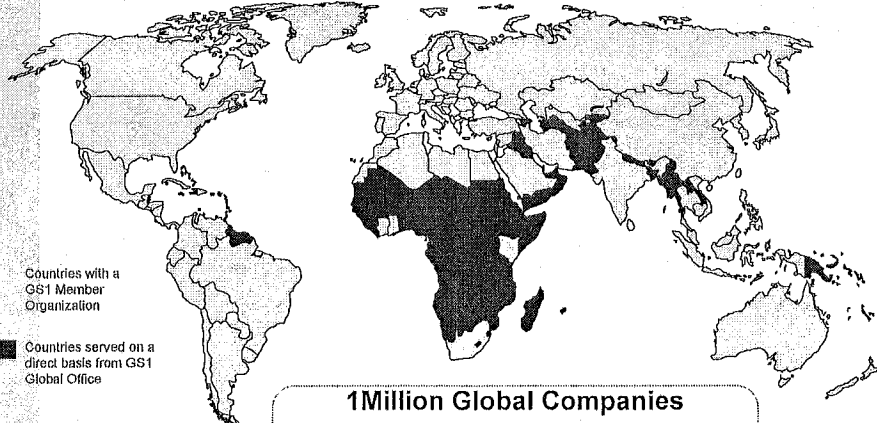
 Global standards for automatic identification <small>RAPID AND ACCURATE ITEM ASSET OR LOCATION IDENTIFICATION</small>	 Global standards for electronic business Messaging <small>RAPID, EFFICIENT & ACCURATE BUSINESS DATA EXCHANGE</small>	 Global Standards for data Synchronisation <small>STANDARDISED, RELIABLE DATA FOR EFFECTIVE BUSINESS TRANSACTIONS</small>	 Global Standards for RFID-based Identification <small>MORE ACCURATE, IMMEDIATE AND COST EFFICIENT VISIBILITY OF INFORMATION</small>
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3




GS1 around the world

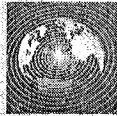


Countries with a GS1 Member Organization
 Countries served on a direct basis from GS1 Global Office

1 Million Global Companies
104 Member Organizations.
155 Countries served.
Local services, global reach.



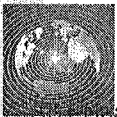
4



About GS1 US

- Formerly known as the UCC
 - Established 1973 (think U.P.C.)
- Implements the GS1 System in the U.S.
 - 23 industries, 280,000 members in U.S.
 - 18,000 identified healthcare members in U.S.
 - Uniquely identify products, assets and locations
 - Bar codes, EPC, e-Commerce, UNSPSC®
- Voluntary, not-for-profit, member driven

5

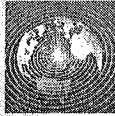


GS1 Healthcare US – Relation to GS1 Healthcare

- **GS1 Healthcare Role:**
 - Global focused
 - The Standards Development per Roadmap
 - Ensuring global standards harmonization
 - Communication on global standards and activities
- **GS1 Healthcare US Role:**
 - US focused
 - Primary customer contact for US based companies / divisions and regulators
 - Drive adoption / implementation
 - Non-voting comment to global standards development

6

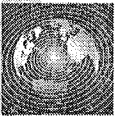




Drive adoption / implementation?

- Pilots
- Business cases
- Education
- Solution provider outreach – identify product needs, minimum software support abilities, etc.
- Scorecards
- Advise US regulators
- Coordinate with existing industry groups
- Implementation guidelines
- Drive R&D

7



User Overview - 23 Sectors



Public Sector

- Defense and Homeland Security



Publishing

- Books, magazines, maps, calendars, greeting cards



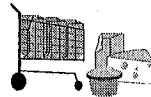
Retail - General Merchandise, Apparel, and Specialty

- Apparel and Fashion Accessories
- Audio/Video
- Furniture (indoor)
- Hardline Merchandise/Home Accessories (Home Accessories, General Merchandise, Toys & Games, Baby Products, House wares, Office/School Supplies, Hobbies, Domestic/Linens, Seasonal Products)
- Cosmetics and Fragrances
- Leisure Industries (Outdoor Furniture/BBQ Grills & Accessories/Wood/Ice Chests/Environmental, Sports Equipment/Physical Equipment, Lawn & Garden, Marine Accessories)
- Music Products - Instruments and Sheet Music



Healthcare and Pharmaceuticals

- Over-The-Counter
- Pharmaceuticals
- Medical/Surgical



Grocery & Foodservice

- Food and Beverage, including Foodservice
- Alcohol Beverage



Durable Products

- Automotive
- Building Materials (Building Supplies/Home Improvement)
- Information Technology/Computers (Computer Hardware/ Software/ Electronics)
- Photographic Equipment/Cameras/Binoculars/ Telescopes

Other

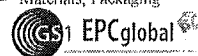
- Service Industry (Market Research)
- Utilities (Power Transmission)

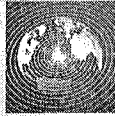


Industrial/Commercial

- Agriculture (Agricultural/Farming, Tobacco)
- Chemicals (Household and Industrial Chemicals)
- Maintenance-Repair-and-Operation, Raw Materials, Packaging

8

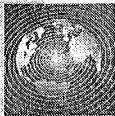
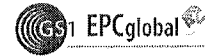




Early Market Adopters

Retail	Consumer Goods	Food & Beverage	Healthcare & Life Sciences	Electronics & High Tech	Logistics & Transport
WAL-MART	P&G Gillette	General Mills	Johnson & Johnson	Gateway	FedEx
CVS	Kimberly-Clark	Kellogg's	Abbott Laboratories	IBM	UPS
Albertsons	Sam Lee	Coca-Cola	Pfizer	hp invent	UNITED STATES POSTAL SERVICE
TARGET	Maytag	Dole	Baxter	M	DHL
BEST BUY	Elizabeth Arden	Andersen	Wyeth	Microsoft	MAERSK LINE

9

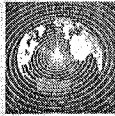


Emerging New Industries

Aerospace & Defense	Chemical	Industrial	Footwear & Apparel	Automotive
BOEING	DOW	3M	PERRY ELLIS	GOODYEAR
LOCKHEED MARTIN	ROHM HAAS	KOMATSU	JOCKEY	MICHELIN
Honeywell	ExxonMobil	PORTER CABLE	Levi Strauss & Co.	JOHN DEERE
GE	bp	Weyerhaeuser	RUSSELL	JOHN DEERE
Pratt & Whitney	Chevron	BLACK & DECKER	VF Corporation	

10





Healthcare – who we are working with ...

•Industry

- Pharmaceutical Manufacturers
- Medical Device Manufacturers
- Distributors
- Retail Pharmacies
- Hospitals
- GPOs

•Regulatory

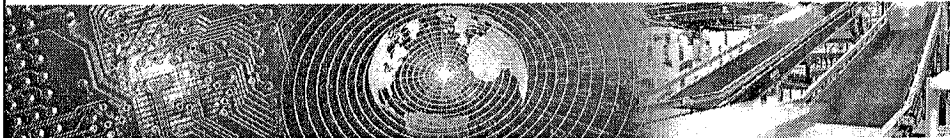
- FDA (Pharma, Med Devices)
- State Boards of Pharmacy
- DEA, EPA, FCC

•Associations

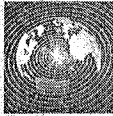
- AHA
- BIO
- CSHP
- HDMA
- HIMSS
- NACDS
- PhRMA

•Universities

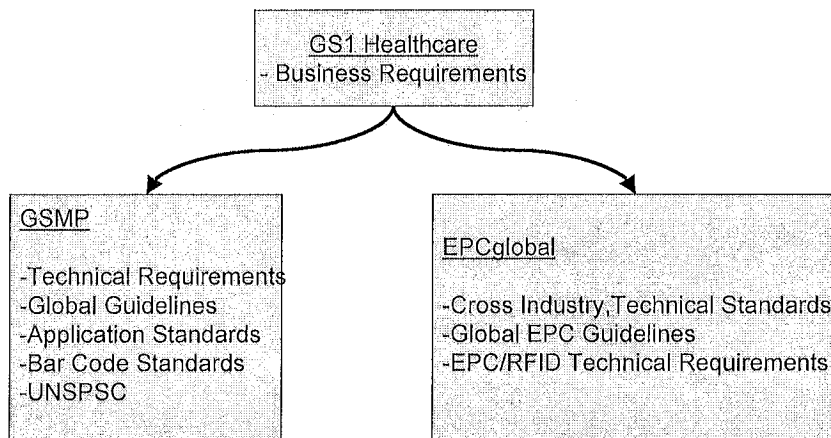
- MIT – Auto-ID Labs
- Drexel University
- Stanford University
- University of Wisconsin
- University of Eindhoven
- University of Arkansas



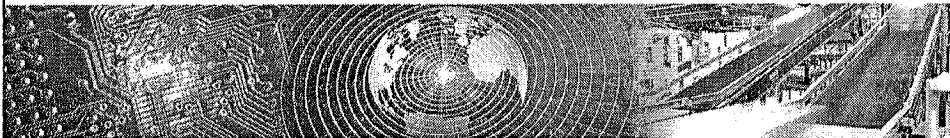
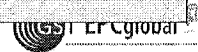
Standards Development



Standards Development Flow For Healthcare related Standards

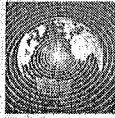


13

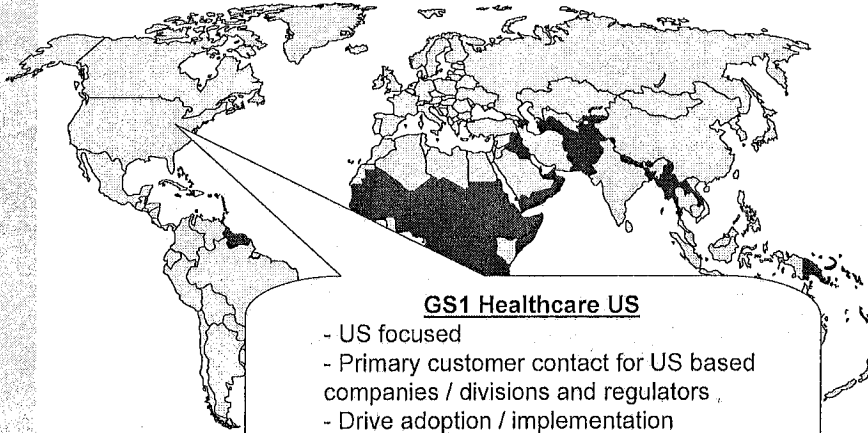


Standards Adoption





GS1 Healthcare US...



GS1 Healthcare US

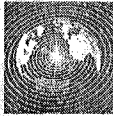
- US focused
- Primary customer contact for US based companies / divisions and regulators
- Drive adoption / implementation
- Non-voting comment to global standards development

15

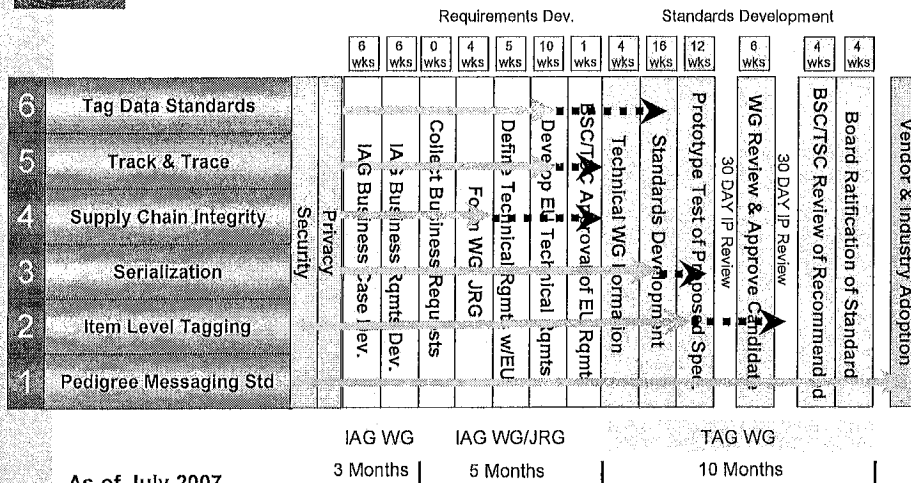


EPCglobal Healthcare Standards





Standards Update



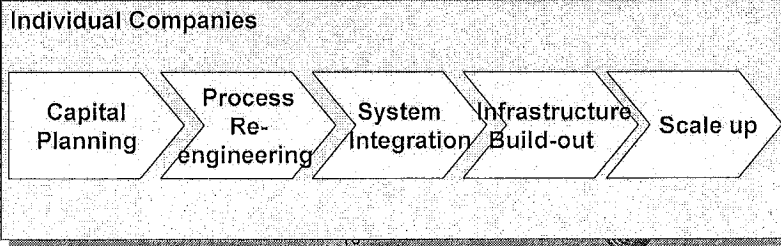
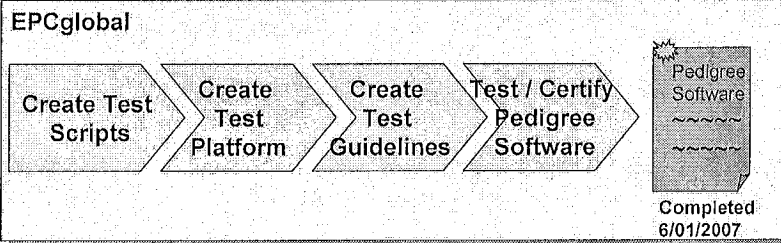
17

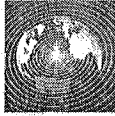


Post Ratification Activities

Example: Pedigree Messaging Standard

Pedigree Standard Ratified January, 2007





Standards Update

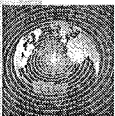
6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

Status:

- **Ratified standard – 01/2007**
- Certification Program - 3 companies certified
 - ✓ Axway
 - ✓ rfxcel
 - ✓ SupplyScape
- Education and awareness web seminars

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

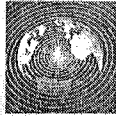
Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment.

Status:

- HF & UHF initiatives underway to provide uniform air interface protocol at item level.
- HF Standard expected '08.
- Completed vote for item level tagging requirements document
- Ratification of standard anticipated 1Q/07
- Anticipate silicon available for prototyping 2Q08

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Standards Update

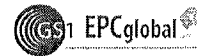
6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements for the EPC identifier to be encoded on an RFID tag.

Status:

- Pharma Requirements complete. Identified 2 GS1 identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.
- Collaborating with GS1/HUG via the "Global Healthcare Initiative" -- starting with Serialization.
 - Joint HUG/HLS Work Team
- Medical Devices, Biologics & other Business Requirements started

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Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

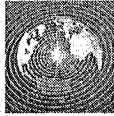
Define requirements and/or guidelines for authenticating and decommissioning tags consistent with optimizing tag utility and consumer/patient privacy.

Status:

- Predominately HLS, however, cross industry work group expected
- Authentication and decommission alternative scenarios identified
- Anticipate completion by end of October

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Standards Update

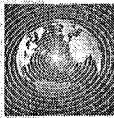
6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges completed
- Integrate with GS1 Traceability efforts
- Track & Trace to be interoperable with Pedigree Model
- Additional use cases addressed:
 - Repackers
 - To be done: 3rd Party Logistics Providers & Product Recall
- Sub-team within Supply Chain Integrity focused on security and pedigree integration
- Data Sharing Strategy & Guidelines will be addressed in Data Exchange JRG
- Common vocabularies and location identifiers incorporated into just ratified EPCIS Standard

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Standards Update

6	Tag Data Standards
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

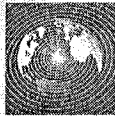
Tag Data JRG focused on defining additional user memory requirements for tags (ie. Lot Number, Expiration Date).

Status:

- Work underway. Defining common data structure that can be used by all industries
- Captured business requirements
- Comment phase approved
- Specification phase started

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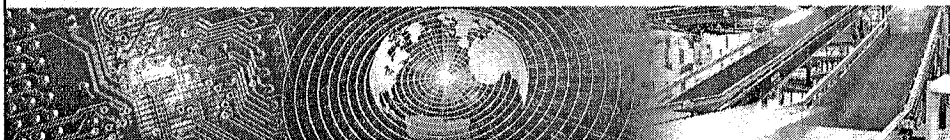




Industry Adoption Task Force Executive Summary

- **Mission:**
 - Define a 'starting set' of guidance for industry trade associations
 - Work closely with EPCglobal and GS1.
 - Educate and hand-off the Roadmap to industry trade associations.
- **Objectives:**
 - Guidance on: Unique Identification based on Serialization.
 - Guidance on: Carrier and Auto-Identification Alternatives
 - Guidance on: Providing Pedigree information:
 - Guidance on: Trading Partner Action Steps for Adoption
- **Timeline:**
 - Document presented to numerous groups
 - Comments resolved
 - Document to be published December 2007

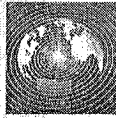
25



EPCglobal HLS Update Follow up Items

Follow Up Items
From
March 8, 2007 Pedigree Workshop
with
Subset of California Board of Pharmacy





Follow Up Items Summary Update

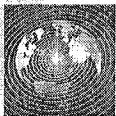
Current Status

Weekly conference calls to work on follow up items

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Assign Responsibility	Document & Identify Item	Status
Individual company	Business Practice	On going
Pedigree WG	Supported by Current Standard	Completed
Pedigree WG	Supported by Current Standard	Completed
Industry Assoc	Supported by Current Standard	Completed
Pedigree WG	Supported by Current Standard	Completed
Individual company	Business Practice	Completed
Industry Pedigree WG	Standard enhancement	Completed
Individual company	Supported by Current Standard	Completed

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1. Unit Dose Serialization Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Mfgs sellable unit may be "broken down" and sold as eaches.

Issues:

1. How are the eaches serialized
2. What is the impact to Repackers
3. How will Repackers continue the pedigree

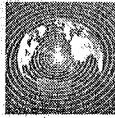
Assignment: Individual Company

Status:

- Business process issue for Supply Chain stakeholders to address level of serialization

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2. Receipt of Partial Shipments Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Orders are not always received complete, having likely pedigree implications.

Issues:

1. How often does this occur
2. What pedigree or business process changes may be required

Assignment: Pedigree Workgroup

Status:

- Current Pedigree standard addresses partials receipts



3. Drop Shipments Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Mfgs ship certain products to end-customers, while billing goes through wholesalers.

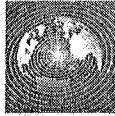
Issues:

1. Where should the pedigree be sent
2. What transaction information should it reflect

Assignment: Pedigree Workgroup

Status:

- Current Pedigree std addresses drop shipments



4. Sign & Certify Inbound Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Signature and certification of in-bound shipments, as well as out-bound.

Issues:

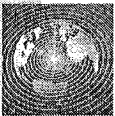
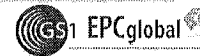
1. Evaluate the implications of not using inference

Assignment: Industry Associations

Status:

- Standard supports signing requirements for in-bound and out-bound

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5. Resale of Returned Product Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: There are times when saleable product is returned by the Whlstr to the Mfrg and may be resold by the Mfrg.

Issues:

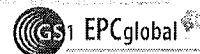
1. Customers may not want returned product if the pedigree must reflect the previous distribution of the product.
2. How should a pedigree treat this transaction – reflect all previous movement of the product, or start anew when sold by the Mfrg
3. What documents, processes, controls and enforcement would be required

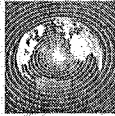
Assignment: Pedigree WG

Status:

- Pedigree standard addresses Resale of Returns

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6. Intra-Company Transfers Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Pedigree Status for intra-company transfers into CA.

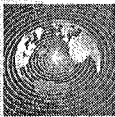
Issues:

1. Product sold to a Whlsr to an out-of-state location that does not require a Mfgr originated pedigree may be intra-company transferred to CA.
2. What are the CA pedigree implications

Assignment: Individual Company

Status:

- Standard supports manufacturer and/or wholesaler originated pedigrees



7. Voided Pedigrees Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

Scenario: Pedigree needs to be updated or changed to correct simple administrative errors such as shipping wrong product or incorrect serial number.

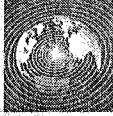
Issues:

1. What is the process of voiding pedigrees where an error has occurred, or a product has been returned
2. How are pedigrees for products marked for destruction managed

Assignment: Industry & Pedigree WG

Status:

- Identified as a pedigree management issue
- Initiating Work Group to address issue, in the interim, Standard provides guidelines & best practices



8. Inference Update

1	Unit Dose Serialization
2	Receipt of Partial Shipments
3	Drop Shipments
4	Sign & Cert. Inbound
5	Resale of Returned Product
6	Intra-Company Transfers
7	Voided Pedigrees
8	Inference

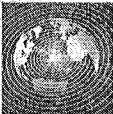
Scenario: Whether inference will be allowed at any step requiring "certification of the receipt", meaning that the receipt is positively affirming that they received all of the products specified in the pedigree without physically verifying all serial numbers.

Issues:

1. Does the pedigree std allow two separate signature events for one receipt step (one to receive, one to certify at a later date).
2. What is the Industry's view on inference and it's application
3. Is there a time limit from inbound receipt inference until all unique ID numbers have been certified


Assignment: Industry Adoption Workgroup
Status:

- Establishing a set of inference recommendations


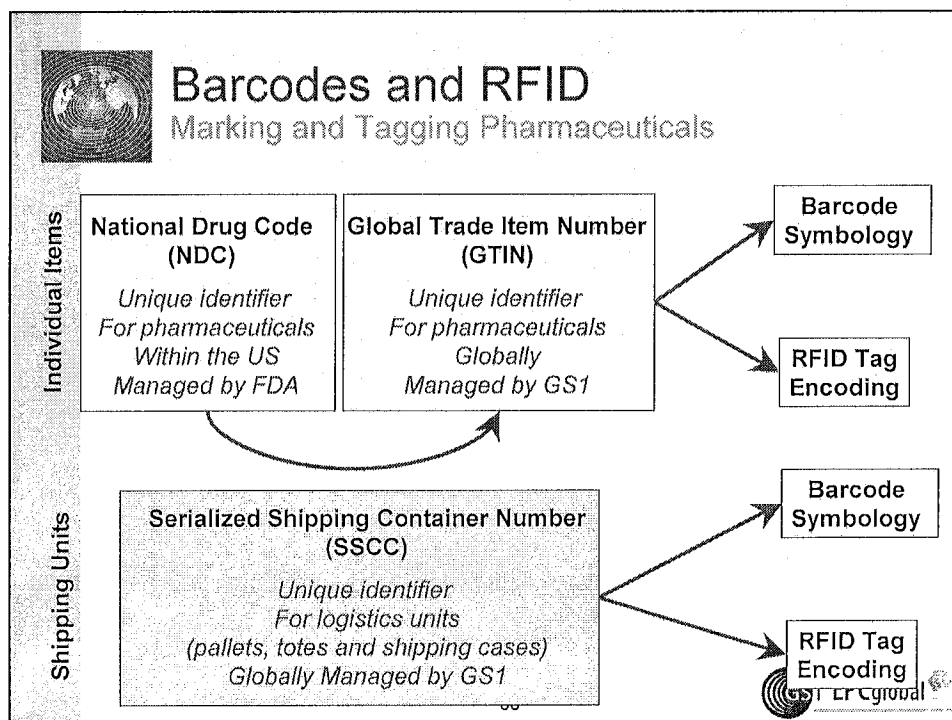


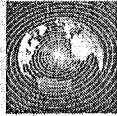
Next Step

- In process of scheduling another pedigree workshop with the following recommended objectives:
 1. Review status of the work on the follow up items in detail,
 2. Discuss impact to standards, and
 3. Review work of the Industry Adoption workgroup



Electronic Tagging and Marking Options



Barcodes and RFID

Differences and similarities

- Overlapping uses
- Different development trajectories
- Distinct reasons for choice
 - Thompson Memorial Hospital example

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Barcodes and RFID

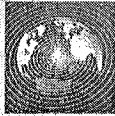
Differences in Barcode types

- Linear Barcodes:
 - Commonly seen in retail and in logistics
 - Usually read by laser scanners – can be read by optical scanners
 - Size increments as additional data is stored
 - Large installed base
- 2D Barcodes:
 - Used in Pharmaceuticals, documents, retail
 - Read by optical scanners
 - Small size
 - Redundant data for fault tolerance
- Mixed types:
 - Used in retail for loose items (fruit)
 - Portions can be read by laser scanner. Serialized portion can be read by optical scanner
 - Relatively small size



40

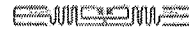




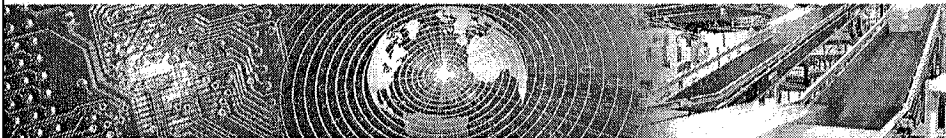
Barcodes and RFID

Differences in RFID types (passive)

- Ultra High Frequency:
 - Can be read from 0 – 5 meters
 - Fastest read speed
 - Reading around liquids and metals is a challenge (but not impossible)
 - Used in Pharmaceuticals, surgical sponges, etc.
- High Frequency (HF):
 - Used in Pharmaceuticals, books, access control
 - Moderate read speed
 - Usually larger than UHF
- Low Frequency (LF):
 - Used in manufacturing processes, access control
 - Slowest read speed
 - Very simple antenna design



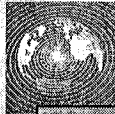
41







"The nice thing about standards is that there are so many to choose from."

... Thomas Rittenhouse, former CEO of the
Uniform Code Council (GS1)






Bar codes that do not support serialization

Carrier	Example	Data	Use Case	Other
UPC-A		GTIN-12	•Retail Point-of-sale	•Linear scanner
UPC-E		GTIN-12	•Retail Point-of-sale	•Linear scanner
EAN-13		GTIN-13	•Retail Point-of-sale	•Linear scanner
EAN-8		GTIN-8	•Retail Point-of-sale	•Linear scanner

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Bar codes that do not support serialization




Carrier	Example	Data	Use Case	Other
ITF-14 Type of Interleaved 2 of 5		GTIN-14	•Non-retail POS items (primarily preprinted corrugate boxes)	•Linear scanner

44








Bar codes that do support serialization

Carrier	Example	Data	Use Case	Other
GS1-128		<ul style="list-style-type: none"> •All GS1 identification numbers including application identifiers, as required •Max: 48 a/n characters •Serial Number 20 characters max 	<ul style="list-style-type: none"> •Non-retail POS items •Logistics units (SSCC) 	•Linear scanner
GS1 DataBar™ [Reduced Space Symbology (RSS)]		<ul style="list-style-type: none"> •All GS1 identification numbers including application identifiers, as required •Max: 74 a/n characters •Serial Number 20 characters max 	<ul style="list-style-type: none"> •Loose produce •Variable measure items (meat/deli) •Coupons •Very small healthcare items 	•Linear scanner
GS1 Data Matrix		<ul style="list-style-type: none"> •All GS1 identification numbers including application identifiers, as required •Max: 2335 a/n characters •3116 num characters •Serial Number 20 characters max 	<ul style="list-style-type: none"> •Direct part marking •Very small healthcare items 	•Image scanner required

45

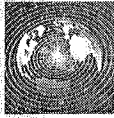


RFID tags that do support serialization

Carrier	Example	Data	Use Case	Other
EPC Gen 2 UHF passive Frequency 860-960 MHz		<ul style="list-style-type: none"> •All GS1 identification numbers including application identifiers, as required •No limit on user memory size determined by cost •Current serial number capacity 200B on 96 bit tag 	<ul style="list-style-type: none"> •Item level •Logistics 	<ul style="list-style-type: none"> •Range < 5m •Rewritable (under password protection) •Non-line of sight •Authentication •Kill capability
EPCglobal HF passive (under development) Frequency 13.56 MHz		<ul style="list-style-type: none"> •All GS1 identification numbers including application identifiers, as required •No limit on user memory size determined by cost •Current serial number capacity 200B on 96 bit tag 	•Item Level	<ul style="list-style-type: none"> •Range < 2m •Rewritable (under password protection) •Non-line of sight •Authentication •Kill capability
EPC Active Tag (under development) Frequency 433 MHz		<ul style="list-style-type: none"> •All GS1 identification numbers including application identifiers, as required 	•Logistics	

46

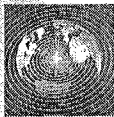




GS1 Serialization Standards

- A serial number, identified with AI 21, is an alphanumeric field of up to 20 characters.
- The capacity of a 20 character serial number is huge.
 - The capacity of an all numeric serial number is 100 quintillion (100×10^{18}).
 - The capacity for an alphanumeric serial number is 13.36749 nonillion (13.36749×10^{30}) when just using 0 to 9 and A to Z.
 - If all 82 alphanumeric characters are used, the serial number has a capacity of 188.9196 undecillion (188.9196×10^{38}).
- The serial number must be unique in relation to the Global Trade Item Number® (GTIN®).
 - Example, serial number 1098765432AC may be associated with both GTIN 00614141123452 and GTIN 00614141999996.

47

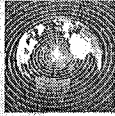


GS1 Serialization Standards (2)

- The serial number is NOT to be parsed by trading partners.
 - There is no provision in the standard to support or enable this.
 - It is also contrary to basic GS1 principles that data elements are not to be parsed.
- Manufacturers may construct the serial number in anyway they see fit, including the use of internal logic or intelligence.
 - There exist no limitations or rules on serial number construction in GS1 standards.
- The SGTIN can always be represented as GTIN (AI 01) plus Serial Number (AI 21).
- The SGTIN-96 structure limits the serial number (AI 21) to a defined subset.
 - This subset is all numeric 38 bit field or 274,877,906,943 unique numbers.
 - This subset requirement exists due to chip size and cost considerations.

48

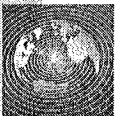




GS1 Serialization Standards (3)

- The SGTIN-198 structure completely supports the serial number (AI 21) - an alphanumeric field of up to 20 characters.

49

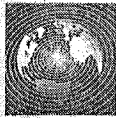


Serialization Implementation Thoughts

- The GS1 community should build applications that support a serial number field of 20 characters.
- If a manufacturer has applied an Electronic Product Code™ (EPC) tag to a product and it is bar coded, then the information must match. Specifically, the GTIN must match and the serial number must match.
- Manufacturers that are unable to accept the serial number subset of the SGTIN-96 in an EPC tag will need to specify EPC tags that support SGTIN-198.
- The lot / batch number must be a distinct data element, defined as AI 10, both when bar coded and in an EPC tag, if it intended for trading partners to use. In a bar code it is AI 10 and in an EPC tag it would need to be in user memory. Should a manufacturer wish to include the lot / batch number in the construction of the serial number, this is their choice but the manufacturer can not expect any trading partners to parse out the lot / batch number from the serial number.

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Data Convergence

Bar Code and EPC - Different Data Formats

Different data formats for the same GS1 ID number

Data
Output

00312345678906

0312345.067890.0

urn:epc.id:sgtin:0312345.067890.0

Data
Capture



GS1 ID
Number
Encoded
in Data
Carriers



51

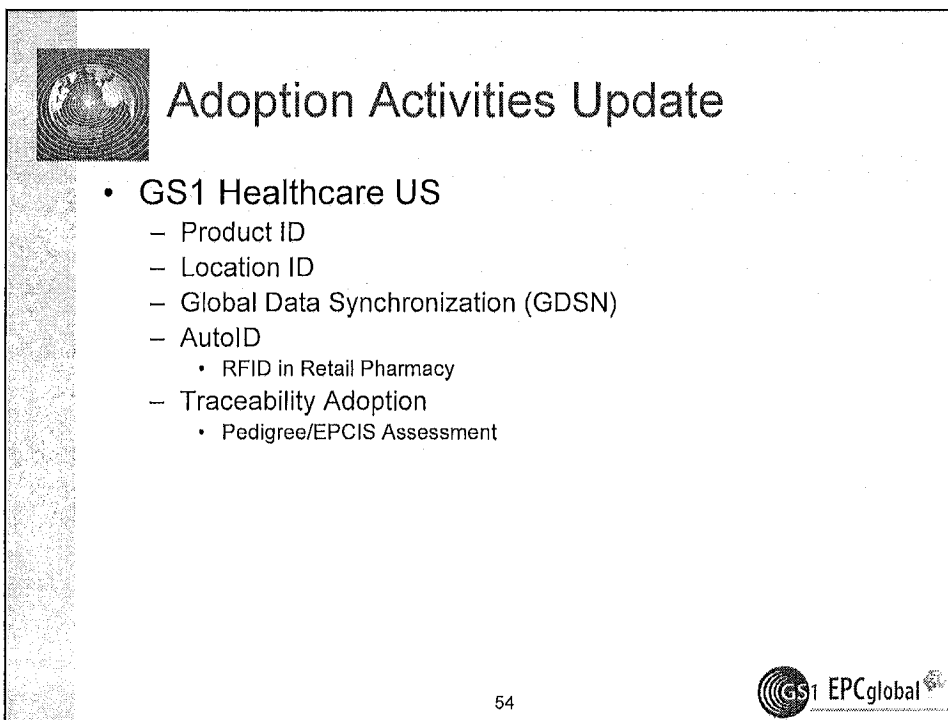
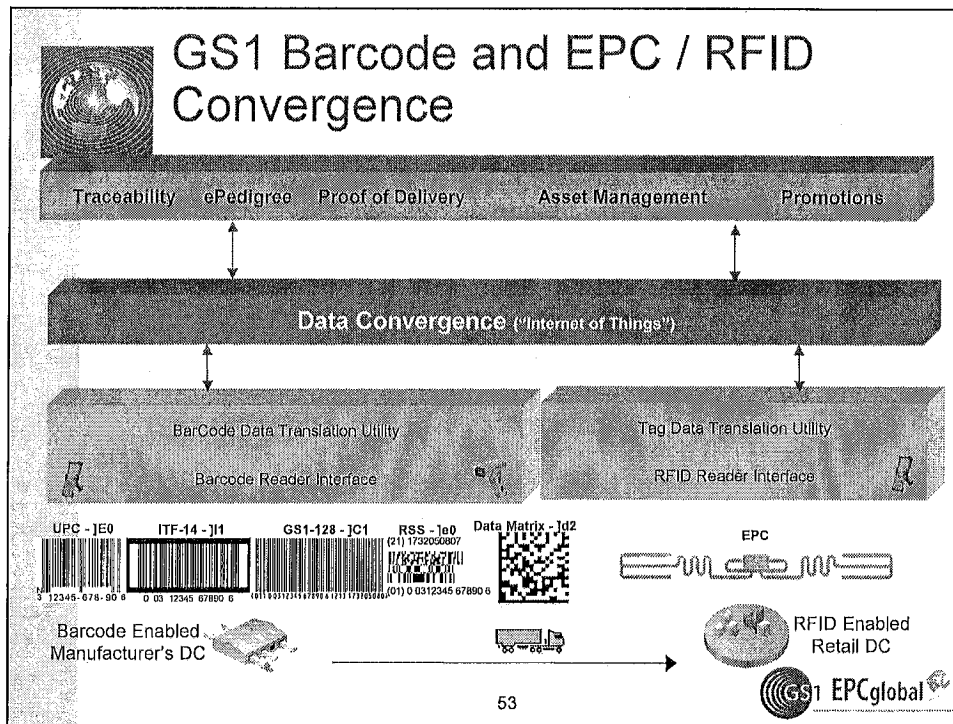


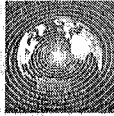
URI Identification System

- URI are the addressing technology standards (IETF) for identifying resources on the Internet or private intranet. Fundamental component of World Wide Web.
 - Uniform Resource Locators (URLs) are addresses for network locations
 - Defines "where"
 - Example: www.gs1.org
 - Uniform Resource Names (URNs). A URN is a name that identifies an information resource on the Internet
 - Defines "what"
 - Example: urn:epc.id:sgtin:0029000.107313.2147488897
 - Foundation for "Internet of Things"

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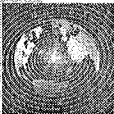


Adoption Activities Update

Pedigree / EPCIS Assessment group (1/2)

- EPCglobal Pedigree Messaging standard is the only standard that meets FDA, State of Florida, State of Nevada and the State of California Pedigree regulations.
- In April, EPCglobal ratified the EPCIS standard.
- The EPCIS standard has been used to address a number of business issues (i.e. Proof of Delivery, Vendor managed Inventory, etc.) and improve sharing of product movement data within supply chains and company processes.
- A number of healthcare End User companies and Solution Provider Companies have approached EPCglobal concerning the possibility of using EPCIS in conjunction with the Pedigree Messaging standard to address Pedigree regulations.

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Adoption Activities Update

Pedigree / EPCIS Assessment group (1/2)



- We have researched some material on the subject and have concluded that there may be possibilities in this type of approach.
- GS1 US and EPCglobal North America, through our GS1 Healthcare US initiative, will form a task force to assess the applicability of EPCIS within a Pedigree environment, determine compatibility with the current Drug Pedigree Messaging Standard and decide whether a US guideline or global standard would best fit the needs of the community.
- Once a conclusion is reached, GS1 Healthcare US will either continue the work towards the creation of a US guideline or present the findings to GS1 Healthcare (the global standards requirements body of GS1) for standards development.
- GS1 Healthcare US will hold a preliminary call on the subject of a "Pedigree / EPCIS Assessment Task Force" on December 13, 2007 at 2:00pm EDT. Details of this call will be available shortly.

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Pedigree Messaging Standard

Pedigree / EPCIS Assessment - Background


Pedigree Messaging Standard sample

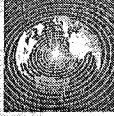
```

pedigree
  receivedPedigree Id="ReceivedPed-1"
    documentInfo
      serialNumber
      version
    pedigree
      shippedPedigree Id="ShippedPed-1"
        documentInfo
          serialNumber
          version
          InitialPedigree
            serialNumber
            productInfo
            itemInfo
          ItemInfo
          transactionInfo
            senderInfo
            recipientInfo
            transactionIdentifier
            ...
          signatureInfo
            Signature (Manuf. Signs: ShippedPed-1)
          receivingInfo
          signatureInfo
            Signature (Wholesaler Signs: ReceivedPed-1)

```

**Pedigree initiated by
Manufacturer and received
by Wholesaler**





Pedigree / EPCIS Assessment - Background

Pedigree Messaging Standard – core elements

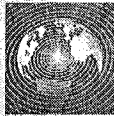
- Document Info
 - Pedigree identifier
- Product Info
 - e.g. Product name, dosage form, etc.
- Item Info
 - e.g. Lot number, expiration date, serial number
- Transaction Info & Receiving Info
- Signature
- Shipped Pedigree
- Received Pedigree
- Initial Pedigree
- Repackaged Pedigree

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EPCIS Standard





Pedigree / EPCIS Assessment - Background

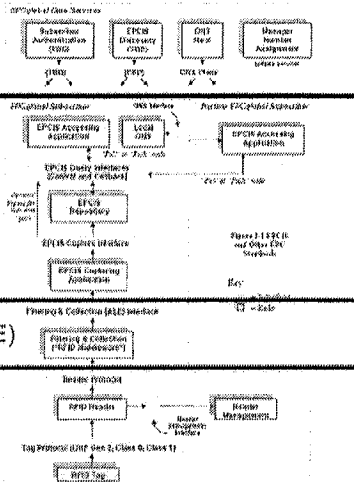
EPCIS - EPCglobal Network standards

2007 – Discovery Services & Subscriber Authentication

2006-07 – Electronic Product Code Information Service (EPCIS)

2005-06 – Filtering & Collection (ALE)


2005-06 - Tags & Readers





Pedigree / EPCIS Assessment - Background

EPCIS

- Cross-Industry Standard
- EPCIS events answer 5 questions ...
 - Who
 - What
 - Where
 - When
 - Why
- EPCIS allows trading partners to "ask" for certain data about product disposition
 - Subscribe
 - Ad Hoc query
- Used by companies to ask internal questions and externally to communicate with Trading Partners
- *In the near future, you may use EPCIS in the form of ...*
 - Supply Chain
 - Hospital and Pharmacy applications




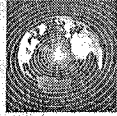
Pedigree & EPCIS

Pedigree / EPCIS Assessment Pedigree and EPCIS

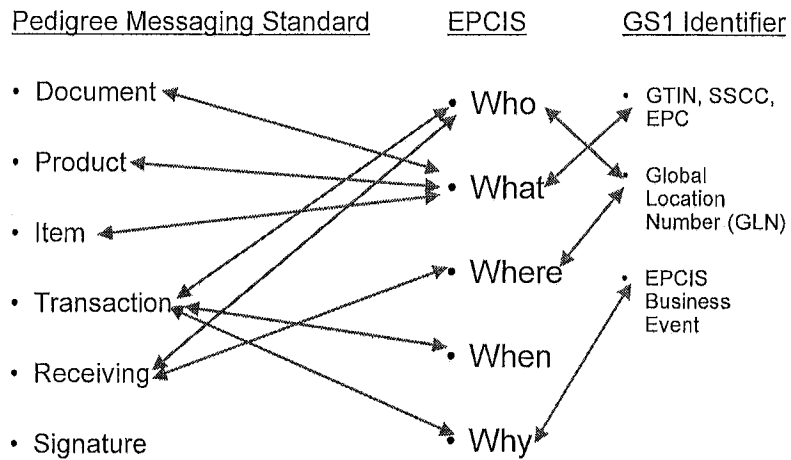
<u>Pedigree Messaging Standard</u>	<u>EPCIS</u>
• Document	• Who
• Product	• What
• Item	• Where
• Transaction	• When
• Receiving	• Why
• Signature	



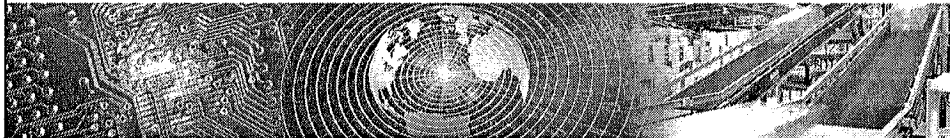


Pedigree / EPCIS Assessment

Pedigree, EPCIS and GS1 Identifiers



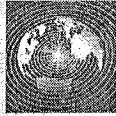
65



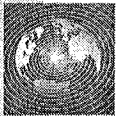
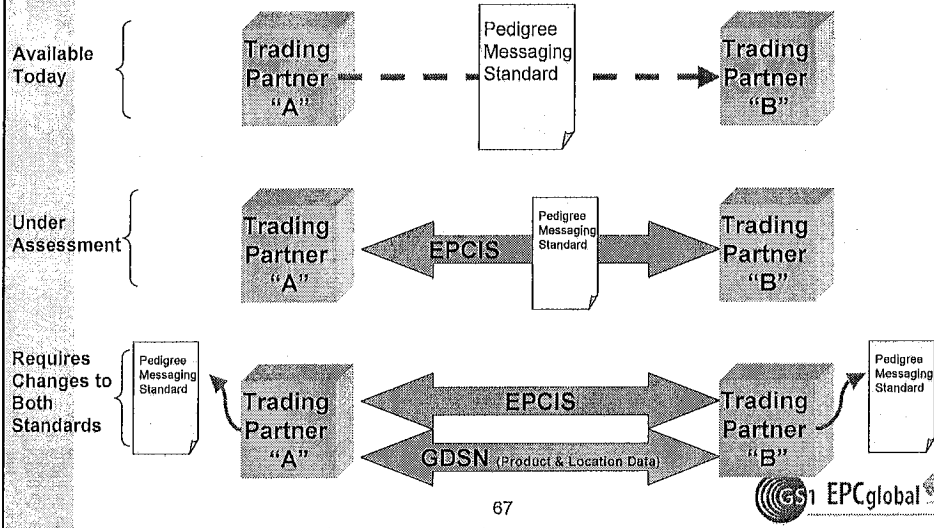
GS1 Healthcare US Pedigree / EPCIS Assessment group

Possible Outcomes






Pedigree / EPCIS Assessment Group Architectural proposals received




Pedigree / EPCIS Assessment Group Possible recommendations

- US Guideline on how to use both the Pedigree Messaging Standard and EPCIS Standard to satisfy Pedigree regulations
- Global Guideline on how to use both the Pedigree Messaging Standard and EPCIS Standard to satisfy Pedigree regulations
- Global Standard on how to use both the Pedigree Messaging Standard and EPCIS Standard to satisfy Pedigree regulations



Questions?



- Draft -

Aegate: increasing confidence in patient safety

California Board of Pharmacy
December 5th 2007



Public

Secure Brands. Secure Business. Secure Patients.

Contents

- Patient Safety
- Current e.pedigree legislation
- How can Authentication help?
- Aegate: Authentication progress across Europe
- **Proposed Californian approach**
- Summary
- Next Steps

Patient Safety is Non-Negotiable

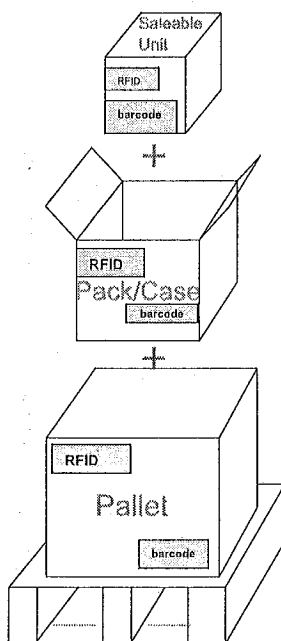


99% OK is not OK

Current environment is not conducive for patient safety

3

Complexity exists with current e-pedigree approach



- Requirement to establish an e-pedigree for each saleable unit makes the approach more complex
- Industry are concerned about their ability to meet the timelines ~ 5 to 7 years ^{*1}
- Concerns have been raised by one manufacturer over the cost to ensure compliance ~ \$95 to \$100 million ^{*1}
- The different technologies and approaches increase complexity for players in the supply chain ^{*2}
- No inference significantly increases complexity for all parties ("double cost" ^{*2})

^{*1} Pfizer presentation to CBoP 20th Jun 07. ^{*2} Walgreens presentation to CBoP 20th Jun 07

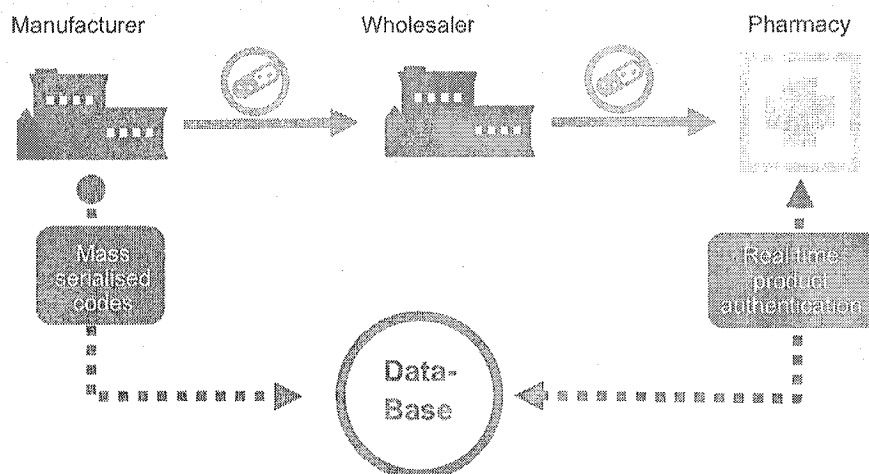
Authentication and case level e-pedigree can help

"Authentication is the process to verify at the point of dispense that the goods being dispensed have the same manufacturer's identifier displayed as present on the secure data base provided by the manufacturer"

- Authentication is complementary to the objectives of the California Board of Pharmacy and e.pedigree
- Authentication is focused on Patient Safety
- Authentication can enhance the e.pedigree objectives
- Authentication can simplify the complexity of e.pedigree
- Authentication could provide justification for inference from saleable unit to case level e-pedigree

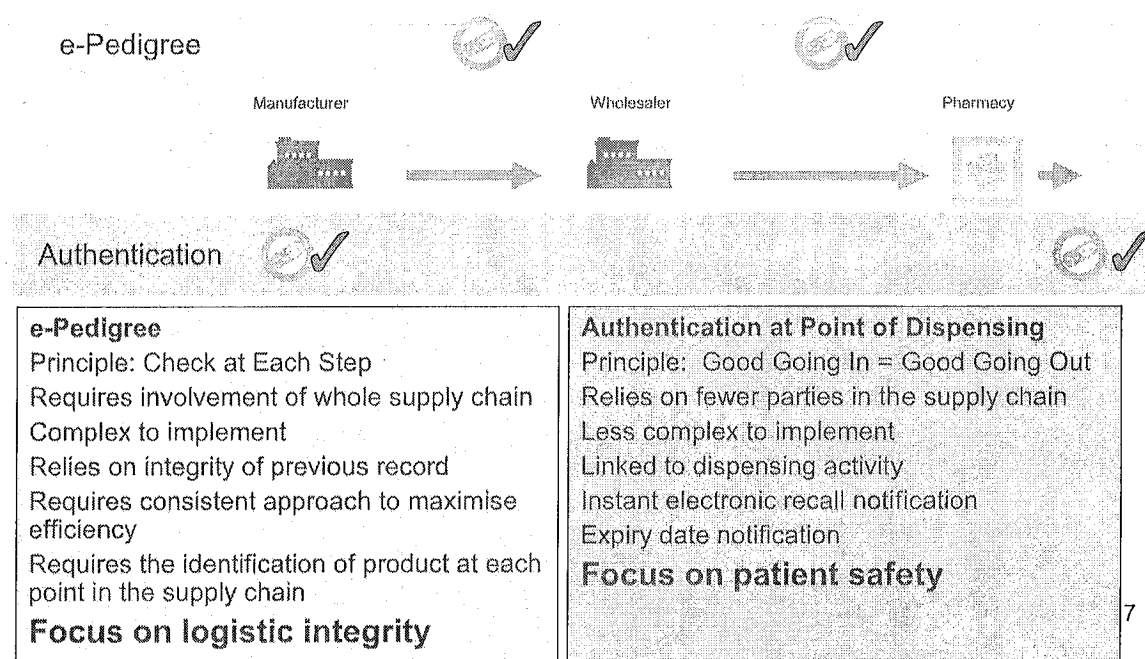
5

Authentication: How does it work?



6

How can Authentication enhance case level e.pedigree?



Aegate: Authentication progress across Europe

Belgium – market total of 5,300 pharmacies

- Launched in 2006
- Access to 70% of Belgian Pharmacies via 4 software providers
- Endorsement from Belgian Pharmacists Association

Greece – market total of 9,500 pharmacies

- Launched October 2007
- Access to 90% of Greek pharmacies via 4 software providers
- Close interaction with Pharmacist Groups

Italy – market total of 17,400 pharmacies

- To launch Q1 2008

18 major pharmaceutical companies, others joining
 260 million unique ids in the system by year end
 1,300,000 authentications per month by year end



Aegate pharmacist feedback

- "I find the information about the recalls and expiry dates very useful: it supports the existing information channels and increases trust and confidence when dispensing products"
- "Although initially I was afraid it would overload my system with messages; this is not the case. The messages that come in are valid. It makes it possible to quickly double check. At the end of the day, you as the pharmacist are the one who decides if, keeping the patient's health in mind, a product can be dispensed or not."

9

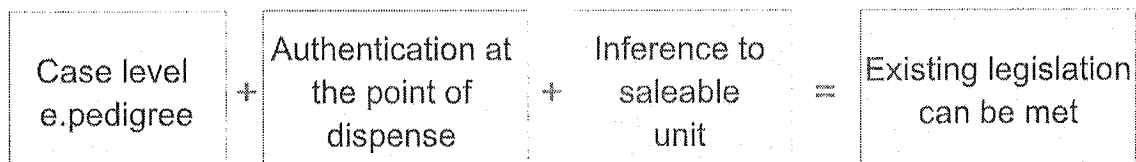


Proposed Californian approach

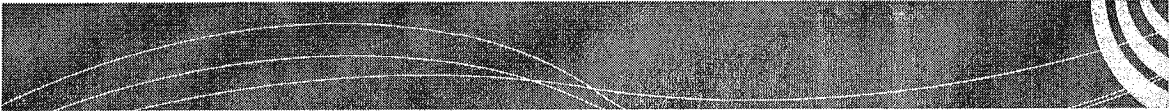
Principle

If the every saleable unit is Authenticated in the dispensary, then inference between case level and the saleable unit can be justified and the existing legislation can be met

Summary



10



What will it require?

- The **Californian Board of Pharmacy** needs to accept the principle of inference from case level to saleable unit provided it is supported by Authentication in the pharmacy
- The **Californian Board of Pharmacy** needs to endorse a coding standard (i.e. GS1)

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Next Steps

- A decision is required from the California Board of Pharmacy regarding Inference and Authentication
- Suggest a Task Force is set up to evaluate this proposal and generate a road map. The working party should consist of:-
 - 2x Solution providers (of which one is Aegate)
 - 3x Manufacturers representatives
 - 2x Wholesaler representatives
 - 2x Pharmacy Chain representatives
 - 1x CBoP representative (observer)
- Tasked to report back and present a paper to the Board meeting on January 23rd 2008 detailing implementation timelines, requirements and benefits

12



Summary

- Authentication at the point of dispense is a viable, timely and complementary solution to improving Patient Safety by securing the supply chain and providing additional value to pharmacy
- Protects the pharmacists and patients
- Supports case level e-Pedigree



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Thank You

Drug Pedigree Laws Real World Applicability Of The Secondary Sector's Experience: Practical vs. Theoretical

Presented by
Gene Alley
Vice President – Regulatory Affairs



NCPD

National
Coalition of
Pharmaceutical
Distributors

1/14/2009



NCPD

Independent Distributors Formed NCPD in June 2006



NCPD

National
Coalition of
Pharmaceutical
Distributors

- **Open to all Prescription Drug Wholesalers**
- **Proactively addresses Pedigree/Rule issues related to independent/secondary distributors**
- **Members distribute to Physicians, Clinics, Pharmacies, Long Term Facilities, Dentists, etc.**
- **Demonstrates the Value Secondary Wholesalers provide**

1/14/2009



NCPD

What Value Do Secondary Wholesalers Provide?

- Personalized Customer Service
- Local Emergency Response
 - i.e., critical need due to disasters like recent CA fires
- Convenience
 - Time Savings
- Extended Terms
- Low minimums
- Competition
- Flexibility
 - Delivery, return policy, price adjustments

1/14/2008

 **NCPD**

Who Do Small Distributors Benefit?

- End Users
 - Lower costs
- Pharmacies and Hospitals
 - Increased profits
- Large Distributors
 - Consolidate purchases from small accounts
- Manufacturers
 - Distribution options
- Local Communities
 - Employment

1/14/2008

 **NCPD**



NCPD

National
Coalition of
Pharmaceutical
Distributors

NCPD supports measures that increase the security of the nation's pharmaceuticals, and urges California to involve all stakeholders in the pedigree implementation process.



1/14/2008

 **NCPD** National Coalition of Pharmaceutical Distributors

NCPD Members.....

- Pedigree positions come from an applied perspective
- Have the most pedigree experience and understand the challenges of the paper pedigree system first hand
- Are willing to work with the CA BoP and other industry stakeholders to provide institutional knowledge on what has & hasn't worked
- Have seen first hand that paper pedigrees have been successful in increasing the security of the supply chain
- Want to be involved in pilot programs with other sectors of the industry
- Realize this is uncharted territory for the CA BoP and wish to be a "sounding board", a resource with practical experience in the day to day challenges of pedigree implementation

1/14/2008

 **NCPD** National Coalition of Pharmaceutical Distributors

Surety Bond Inequities

- **Surety Bonds disproportionately burdens the small distributors; any bond program should be flexible enough to reflect the economic realities associated with small businesses; one size doesn't fit all**
- **Annual revenue figures unrealistic to Medical Surgical Supply Distributors; product mix is usually 80% supplies and equipment and 20% drugs; therefore a \$10MM company sells \$2MM in Rx Drugs, but must buy a \$100K bond vs. a \$25K bond**
- **Multiple state bonds put small distributors at a competitive disadvantage; availability of bond is proportionate to company revenue**
- **Solution: One national surety bond proportionate to revenue (preferred), or a sliding-scale CA bond that is equitable to all**

1/14/2008

 **NCPD** National Council on Prescription Drug Policy

CA Pedigree: Push On, Delay Entirely, Phase In?

- **Patient Safety Must be The Primary Concern**
- **Serialization is a big problem; implementation by 01/09 will be challenging**
- **Pharmacies are dependent on manufacturers to determine what technology to buy, leaving little implementation time**
- **Pedigree with lot numbers has proven to be an extremely valuable tool in increasing the security of the supply chain**
- **Manufacturers are overlooking the ROI that electronic pedigree will provide them**
- **An electronic pedigree without serialization is better than no pedigree in California for another two years**

1/14/2008

 **NCPD** National Council on Prescription Drug Policy

NCPD Recommendations

- Patient Safety Must be THE Primary Concern
- Phased in approach is a must; legislation should be initiated to allow BoP flexibility it needs
- Implement Electronic Pedigree January 1, 2009 with same rules as in current statute
- Delay Serialization until 2011, and phase in on a risk-based strategy
- Make Surety Bond Equitable to ALL distributors
- Include NCPD as one of your many resources to help determine the best method to protect CA consumers

NO Pedigree in Force = CA Consumers Still at Risk!

1/14/2008



**If you let the Perfect become the
Enemy of the Good, NOTHING
will ever be Accomplished**



gene.alley@ncpdusa.org

www.NCPDusa.org

1/14/2008



Representing Independent Pharmaceutical Distributors



Gene Alley – Vice President Regulatory Affairs

About NCPD

The National Coalition of Pharmaceutical Distributors represents and promotes the value of small and independent pharmaceutical distributors with respect to legislatures, regulatory organizations, manufacturers, dispensers, and the community at large through rigorous advocacy in order to preserve the businesses of its members, to ensure distribution system efficiency and to uphold public safety.

www.NCPDusa.org

1/14/2008



December 5, 2007

E-Pedigree Work Group
California State Board of Pharmacy
1625 N. Market Blvd, Suite N219
Sacramento, CA 95834

Ref: E-Pedigree compliance by January 2009

Good afternoon committee members and leadership.

My name is Jeff Schaengold and I am appearing on behalf of myself, as well as a business unit of the Siemens organization.

Siemens is a global leader in Health Sciences, Energy and Industry with global revenue approaching \$200 Billion.

Siemens is either in a number 1 or number 2 global leadership positions in almost every business segment. Most particularly to this audience, Siemens is the world's largest health diagnostics company, one of the leading medical device supplier and a global leader in traceability and IT solutions for healthcare.

Personally, I've been leading the adoption of technologies such as EDI, barcode, RFID and eCommerce for close to 3 decades.

Committee members, I am here to respectfully suggest that all the elements presented to the committee and the State leadership to date, while well meaning, will result in delayed adoption of drug traceability without justifications. The delay beyond January 2009 will jeopardize the lives of Californians every single minute of the day.

What I would like to present to this committee is that traceability is 95% adoption of the serialization principle and 5% deciding on standards.

Committee members, traceability and serialization have existed in aviation, automotive, and electronics for over 70 years without a detrimental impact to the business.

The concept of serialization is not new and it's not expensive.

Serialization of drugs will cost a fraction of a cent per unit. To drug manufacturers the total cost impact of serialization is less than the cost of subsidy of a company cafeteria program.

Siemens Energy & Automation, Inc.

8931 Bay Cove Ct
Orlando, FL 32819

Tel: (407) 876-0581
Fax: (407) 842-7206

Jeff.schaengold@siemens.com

As to the application of a serial number to a drug package, the longest timeline element is equipping the packaging line with the appropriate equipment to print a serial number on the package. It doesn't matter what the structure of a serial number is determined. Serial number formats can be modified, literally, on the fly and older version serial numbers can be read until sunset and new formats can be backward compatible.

Logging serial number data to a server is as simple as logging any event on a company's data network.

Committee members, while standards for serial number formats and decisions of the use of barcode vs. character based vs. RFID for the conveyance of the serial number are beneficial, these factors can not impede adoption of serialization and ePedigree in the State of California.

To that end, Siemens and I are presenting to this committee our commitment to make the resources available to any drug manufacturer or wholesaler that needs to fast-track their package serialization and ePedigree solution to meet the January 2009 date.

With close to 500,000 employees worldwide, Siemens has the resources to provide the IT services and the packaging marking technologies to achieve the targets set for California ePedigree.

To qualify this position of support to the California State Board of Pharmacy, Siemens and I have been developing and leading the development of RFID for over 25 years.

Through acquisitions and internal development, Siemens is the inventor of the datamatrix code that is the default conveyance for machine readable serial number.

Siemens is the global leader in high speed processing of small articles and Siemens is capable of marking, reading and verifying products on a conveyor line faster and better than any company in the world.

Committee members, this is not a commercial for Siemens. This is an offer to Californians from Siemens to lead the improvement of the delivery of drugs to the 30 million citizens that are suffering today because of errors in dispensing drugs and counterfeit drugs.

Siemens Energy & Automation, Inc.

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Orlando, FL 32819
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Tel: (407) 876-0581
Fax: (407) 842-7206

Look to other industries....

Recently, I was at a Wal-Mart in Connecticut. I purchased a printer. As the Wal-Mart clerk scanned the UPC code for the \$25 printer, the POS screen prompted the clerk to scan the serial number.

Committee members, if Wal-Mart can train an entry level clerk to scan a serial number, it is beyond our comprehension that a healthcare delivery person can not be trained to do likewise. Do we perceive the retail clerk to be better trained than a healthcare provider?

A manufacturer of ink jet cartridges can serialize every one of the 100's of millions of cartridges they produce, and we can't serialize oncology drugs?

Fast food restaurants can afford to provide unit dose condiments with a \$1.00 burger and we can't deliver unit dose packaging of \$50 pills ?

We would like to help California draw a line in the sand, committee members, and support the January, 2009 life saving requirement for ePedigree.

As I mentioned earlier, we are ready, willing and able to support any drug producer and wholesaler be compliant with serializing drugs sold in California by January 2009.

There are no caveats in our statement. We are not providing grandfather exceptions or waivers. Siemens is supporting the initiative to have 100% of the drugs sold in California January 2009 serialized and ePedigree ready and we are making the resources available to accomplish the tasks.

Thank you for the opportunity to present our message.

Jeff Schaengold
Traceability Internal Consultant
Siemens Energy & Automation

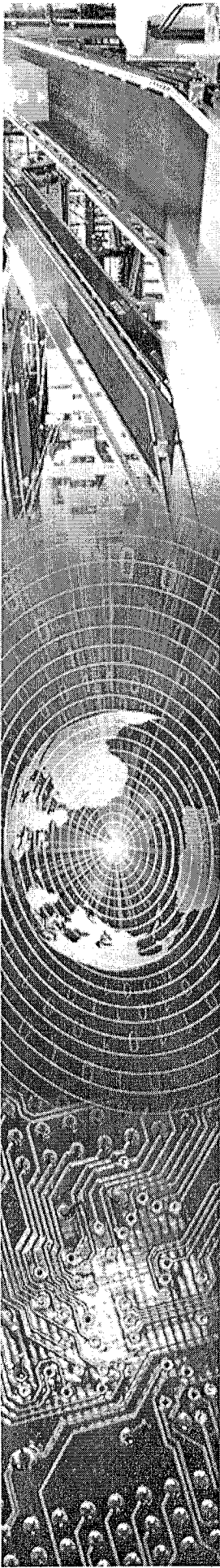
Siemens Energy & Automation, Inc.

8931 Bay Cove Ct
Orlando, FL 32819
Jeff.schaengold@siemens.com

Tel: (407) 876-0581
Fax: (407) 842-7206

Attachment 2

*EPCglobal's Presentation on
Inference, Given December 5, 2007*



Inference Discussion

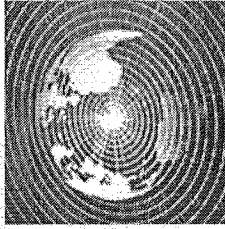
*Excerpt from the
EPCglobal HLS Industry Adoption Roadmap
Final Version v13.1*

Prepared by the EPCglobal HLS Industry Adoption Task Force

For General Release

Published __, 2007

EPCglobal 



Appendix 1

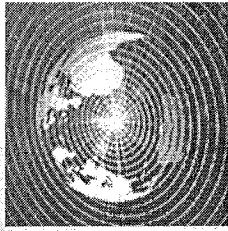
Suggestions: Serialized Inference

Business Problem:

- California SB1476 at Section 4034(b)(3) requires the “name and address of each person certifying delivery or receipt”.
- This ‘certification’ of item-level serial numbers presents new challenges:
 - Line of sight technology would result in opening every case and scanning every item within, since the item serial numbers are not visible.
 - Non-line of sight technology, if less than 100% of the items were read, would result in opening every case and scanning every item within.
 - Opening cases at time of receipt introduces new risks, is time-consuming, and adds costs into supply chain operations.

One Potential Suggestion:

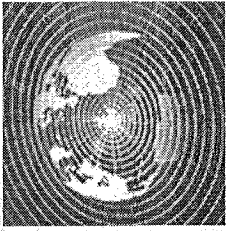
- Inference is one of many mechanisms to enable trading partners to leverage strong supply chain practices to meet these challenges.
- Adoption of any solution to these challenges remains an individual company decision.
- The California BOP has scheduled working sessions with industry to better understand these challenges. Regulatory guidance may result from these working sessions.



IATF Companies / Organizations

The following organizations participated in creation of this deliverable.

<u>Supply Chain Partners</u>	<u>Supply Chain Partners</u>	<u>Trade / Regulatory</u>
<ul style="list-style-type: none"> • Abbott Laboratories • Ahold N.V. • Albertsons • Alcon Laboratories • Allergan • AmerisourceBergen Corp. • AstraZeneca • Baxter Healthcare Corp. • Bristol Meyers Squibb • Cardinal Health • CVS • Dai Nippon Printing • Genzyme Corporation • GlaxoSmithKline • Johnson & Johnson • Ken Traub Consulting LLC 	<ul style="list-style-type: none"> • Kimberly-Clark • Matsushita Electric • McKesson Corporation • Merck & Co. • MetaBiz • Motorola Inc. • NEC Corporation • Nestle S.A. • Pfizer Inc. • Proctor & Gamble • Royal Philips Electronics N.V. • Target • The Dow Chemical Company • Unisys • Upsher-Smith Labs • Walgreens Company 	<ul style="list-style-type: none"> • Auto-ID Labs (MIT) • CPhA • FDA • HDMA • NACDS • NCPA • GS1 Healthcare <ul style="list-style-type: none"> - EPCglobal HLS Community - GS1 HUG Community

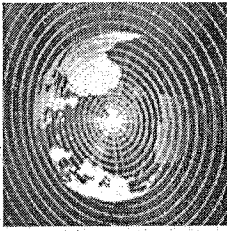


Appendix 1

Suggestions: Serialized Inference Definitions

- Infer (Inference): Conclude from evidence (Webster's Dictionary).
- Working Definition: To infer the serialized number based on information provided by the upstream supply chain, reasonable inspection of the product, and application of the Serialized Inference Rule by the Shipping and Receiving partners.
- Serialized Inference Rule: The process a supply chain partner uses to ensure there is enough evidence to infer the serialized number without physically reading ALL serialized numbers. A Serialized Inference Rule should be defined for each packaging unit (e.g., pallet, case, item, etc.) for the key process steps of Commission/Aggregation, Ship, and Receipt.

Enhance Patient Safety in the supply chain by allowing supply chain partners to leverage the good business practices initiated by manufacturers which are then continued through the supply chain by downstream trading partners.

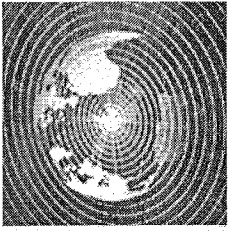


Appendix 1

Suggestions: Serialized Inference

Assumes that each Trading Partner follows good business practices, such as:

- Good manufacturing and good distribution practices.
- Documented controls and Standard Operating Procedures.
- Captures quality metrics to minimize “defects” of inbound and outbound product.
- When process errors are detected, implements changes to those processes to prevent future errors.
- Processes are periodically reviewed for improvement opportunities.



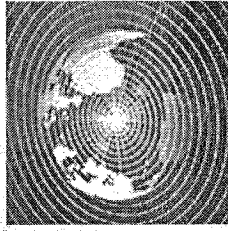
Appendix 1

Suggestions: Serialized Inference

To summarize, Serialized Inference is possible when the following conditions have been achieved:

- A collection (item, full or mixed case, tote, pallet, etc.) is present.
- The collection is identified with a unique serial number, and each member of the collection (item, case, tote, pallet) is also identified with a unique serial number.
- The receiving trading partner receives an electronic communication containing the serialized numbers and the hierarchical relationship of those serialized numbers within the collection.
- The receiving trading partner must have assurance that the collection has remained intact since leaving the last trading partner.
 - If the receiving trading partner has reason to believe that the collection has not remained intact since leaving the last trading partner, then inference should not be used.

These inference suggestions are intended to provide each trading partner with an understanding of how inference can be used by all the various supply chain participants. The application of inference remains an individual business decision.



Appendix 1

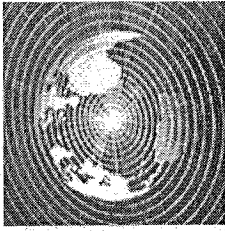
Suggestions: Serialized Inference

Serialized Inference Scenarios:

Designed for transactions between trading partners, however can be applied to intra-company transactions as well.

- Single Item Commission
 - Apply serial number to one single Item.
- Item into Case Commission/Aggregation
 - Apply serial number to Case and build item-to-case hierarchy.
- Case to Pallet Commission/Aggregation
 - Apply serial number to a homogenous pallet comprised of Cases of all one product and build case-to-pallet hierarchy.
 - May be a full pallet or a partial pallet.
- Tote or Mixed Case Commission/Aggregation
 - Apply serial number to Case or Tote containing either a mixture of SKU's or 1 or more items of a single SKU, and build item-to-case hierarchy. Typically conducted as part of a pick/pack/ship operation.
- Mixed Pallet Commission/Aggregation
 - Apply serial number to Pallet of mixed Cases or Totes, and build case-to-pallet or tote-to-pallet hierarchy. Pallet could contain mixed cases and/or full cases. The full cases could be from one product or from multiple products.





Appendix 1

Suggestions: Serialized Inference

Designed for transactions between trading partners, however can be applied to intra-company transactions as well.

Serialized Inference Scenarios:

- Shipments
 - Single Item Shipment (one single item shipped)
 - Case Shipment (all one item)
 - Tote or Mixed Case Shipment (One or more items or mixed items, typically part of a pick/pack/ship operation)
 - Pallet Shipment (all one item on a pallet)
 - Mixed Pallet Shipment (mixed items on a pallet)
- Receipts
 - Single Item Receipt (one single item received)
 - Case Receipt (all one item)
 - Tote or Mixed Case Receipt (One or more items or mixed items, typically conducted as part of a pick/pack/ship operation)
 - Pallet Receipt (all one item on a pallet)
 - Mixed Pallet Receipt (mixed items on a pallet)

Shipments and Receipts of pallet, case, mixed case, and tote assumes the hierarchy and packaging integrity remained intact from the Commission/Aggregation process.



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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Implementation Submission Statement Template

The California State Board of Pharmacy is interested in developing agendas and discussion items for the E-Pedigree Work Group Meetings around items with value to the industry.

Please use the following template headings to provide a description of issues, problems or preferred solutions on implementation issues involving California's electronic pedigree requirements. These statements should be submitted to the board in advance of an E-Pedigree meeting, conforming to the template below:

- Issue/Topic: *Inference*
- Submitted by: *Robert Celeste, Director, Healthcare, EPCglobal North America*
- Background: *Historical overview/framework of current practices in the industry, what are the different scenarios in which this practice or subject area has arisen already, what are the processes employed to date, what members of the supply chain are involved? EPCglobal North America would like to submit the attached presentation on "Inference" to provide a base level of understanding on the subject. EPCglobal's Industry Adoption Task Force recently concluded a body of work that contained general material on inference. That document has been widely distributed to healthcare companies and associations. It is our hope that the material will form a basis for discussion by companies and trade organizations for their point of view on the subject.*
- Challenge presented by timely compliance with California's law:
- Frequency or prevalence of this practice or subject area: *Our understanding through requirements and Use Case development with the industry, is that a fair amount of inference is used by trading partners today.*
-
- A specific discussion of the costs of such implementation, on as many variables as possible (per-unit, per-store, per-facility, per-company) *Our hope is that this information will be useful by companies and associations in developing their specific inference scenarios and costs .*
-
- Desired solution:
- Without the desired solution, what is the potential impact?

- Contact information and date: *Robert Celeste, Director, Healthcare, EPCglobal North America. November 21, 2007.*
-

Note: it is anticipated that these presentations will come, at least initially, from industry associations or other representative associations, so as to capture larger quantities of data or experience and focus the discussions on systemic rather than individual solutions. It is also anticipated that competing concerns of different industry players may need to be suspended to advance the presentations.

Please submit to Virginia Herold at the above address. Thank you.

Attachment 3

*Second Quarterly Update on the
Enforcement Committee Goals for
2007/08*

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1	Achieve 100 percent closure on all cases within 6 months.						
Measure:	Percentage of cases closed.						
Tasks:	1. Mediate all complaints within 90 days (for cases closed during quarter).						
		<u>N</u>	< 90 days	< 120 days	< 180 days	Longer	<u>Average Days</u>
	Qtr 1	211	171	25	12	2	57
			(81%)	(12%)	(6%)	(1%)	
	Qtr 2	90	78	10	2	0	47
			(87%)	(11%)	(2%)	(0%)	
	Qtr 3						
	Qtr 4						
	2. Investigate all cases within 120 days (for cases closed during quarter).						
		<u>N</u>	< 120 days	< 180 days	< 270 days	Longer	<u>Average Days</u>
	Qtr 1	235	167	20	37	11	91
			(71%)	(8%)	(16%)	(5%)	
	Qtr 2	263	165	50	23	25	139
			(63%)	(19%)	(9%)	(10%)	
	Qtr 3						
	Qtr 4						

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Qtr 1	<u>N</u>	< 180	< 270	< 365	> 365
Closed, no additional action	184	171	11	2	0
Cite and/or fine letter of admonishment	237	209	21	7	0
Attorney General's Office	24	15	7	2	0
Qtr 2	<u>N</u>	< 180	< 270	< 365	> 365
Closed, no additional action	146	137	7	1	1
Cite and/or fine letter of admonishment	199	163	15	10	11
Attorney General's Office	8	4	2	2	0
Qtr 3	<u>N</u>	< 180	< 270	< 365	> 365
Closed, no additional action					
Cite and/or fine letter of admonishment					
Attorney General's Office					
Qtr 4	<u>N</u>	< 180	< 270	< 365	> 365
Closed, no additional action					
Cite and/or fine letter of admonishment					
Attorney General's Office					

Objective 1.2	Manage enforcement activities for achievement of performance expectations.						
Measure:	Percentage compliance with program requirements.						
Tasks:	1. Administer the Pharmacists Recovery Program.						
		Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program		
	Qtr 1	18	54	0	3		
	Qtr 2	18	56	61	4		
	Qtr 3						
	Qtr 4						
	2. Administer the Probation Monitoring Program.						
		Qtr 1	Qtr 2	Qtr 3	Qtr 4		
	Individuals	123	121				
	Sites	6	6				
	Tolled	25	31				
	Inspections Conducted	44	56				
	Successfully Completed	2	2				
	Petitions to Revoke Filed	2	0				
	3. Issue all citations and fines within 30 days.						
		N	30 days	60 days	90 days	> 90 days	Average Days
	Qtr 1	188	1	11	77	99	94
			(.5%)	(6%)	(41%)	(53%)	
	Qtr 2	175	1	0	44	130	102
			(.6%)	(0%)	(25%)	(74%)	
Qtr 3							
Qtr 4							
4. Issue letters of admonishment within 30 days.							
	N	30 days	60 days	90 days	> 90 days	Average	
Qtr 1	50	20	24	4	2	38	
		(40%)	(48%)	(8%)	(4%)		
Qtr 2	24	0	4	14	6	87	
		(0%)	(17%)	(60%)	(25%)		
Qtr 3							
Qtr 4							

5. Obtain immediate public protection sanctions for egregious violations.

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	0	0	0
Qtr 2	0	0	1
Qtr 3			
Qtr 4			

6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.

	30 days	60 days	> 60 days	N
Qtr 1	0	0	1	1
Qtr 2	1	0	1	2
Qtr 3				
Qtr 4				

Objective 1.3

Achieve 100 percent closure on all administrative cases within 1 year.

Measure:

Percentage of administrative cases closed within 1 year.

	N	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
Qtr 1	13	5 (39%)	3 (23%)	4 (31%)	1 (8%)	0 (0%)	448 days
Qtr 2	26	16 (62%)	8 (31%)	2 (8%)	0 (0%)	0 (0%)	360 days
Qtr 3							
Qtr 4							

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/08.																																																							
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.																																																							
Tasks:	<div>1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.</div> <table><thead><tr><th></th><th>Number of Inspections</th><th>Aggregate Inspections This Cycle</th><th>Percent Complete</th></tr></thead><tbody><tr><td>Qtr 1</td><td>387</td><td>3,648</td><td>50%</td></tr><tr><td>Qtr 2</td><td>366</td><td>3,758</td><td>52%</td></tr><tr><td>Qtr 3</td><td></td><td></td><td></td></tr><tr><td>Qtr 4</td><td></td><td></td><td></td></tr></tbody></table> <div>2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.</div> <table><thead><tr><th></th><th>Number of Inspections</th><th>Number Inspected Late</th></tr></thead><tbody><tr><td>Qtr 1</td><td>60</td><td>0</td></tr><tr><td>Qtr 2</td><td>61</td><td>0</td></tr><tr><td>Qtr 3</td><td></td><td></td></tr><tr><td>Qtr 4</td><td></td><td></td></tr></tbody></table> <div>3. Initiate investigations based upon violations discovered during routine inspections.</div> <table><thead><tr><th></th><th>Number of Inspections</th><th>Number of Investigations Opened</th><th>Percent Opened</th></tr></thead><tbody><tr><td>Qtr 1</td><td>387</td><td>14</td><td>4%</td></tr><tr><td>Qtr 2</td><td>366</td><td>11</td><td>3%</td></tr><tr><td>Qtr 3</td><td></td><td></td><td></td></tr><tr><td>Qtr 4</td><td></td><td></td><td></td></tr></tbody></table>		Number of Inspections	Aggregate Inspections This Cycle	Percent Complete	Qtr 1	387	3,648	50%	Qtr 2	366	3,758	52%	Qtr 3				Qtr 4					Number of Inspections	Number Inspected Late	Qtr 1	60	0	Qtr 2	61	0	Qtr 3			Qtr 4				Number of Inspections	Number of Investigations Opened	Percent Opened	Qtr 1	387	14	4%	Qtr 2	366	11	3%	Qtr 3				Qtr 4			
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Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	<p>1. Monitor the implementation of e-pedigree on all prescription medications sold in California.</p> <p><i>Sept. 28, 2006: Board convenes third Workgroup on Implementation of E-Pedigree Meeting. Presentations provided by EPCglobal, McKesson, Supervising Inspector Nurse and Johnson and Johnson.</i></p> <p><i>Sept. 30, 2006: Governor signs SB 1476 which delays implementation of e-pedigree requirements until 2009, requires serialization and interoperability and notification to the board whenever counterfeit drugs are discovered.</i></p> <p><i>Oct. 6, 2006: FDA provides presentation on federal pedigree requirements at board-hosted NABP District 7 & 8 Meeting.</i></p> <p><i>Dec. 2006: Board convenes fourth Workgroup on Implementation of E-Pedigree Meeting. Presentations made by EPCglobal, McKesson, AmerisourceBergen and Cardinal. Pilot testing e-pedigree systems underway at each of the three large wholesalers. Standards for electronic pedigree to be finalized by January 2007 by EPCglobal.</i></p> <p><i>Jan. 2007: EPCglobal finalizes electronic messaging standards for electronic pedigrees.</i></p> <p><i>Feb. 2007: EPCglobal convenes regional meeting with hospitals to discuss implementation issues of e-pedigree in these facilities. Hospitals are encouraged to join the board's Workgroup on Implementation of E-Pedigree Meetings.</i></p> <p><i>March 2007: Two board members and executive staff meet with nine EPCglobal representatives to walk through EPCglobal's messaging standards and business scenarios. The standard complies with California's e-pedigree requirements although some questions remain about situation-specific criteria.</i></p> <p><i>Board convenes fifth Workgroup on Implementation of E-pedigree Meeting. Presentations are made by EPCglobal, AmerisourceBergen and SupplyScape.</i></p> <p><i>May 2007: Board presents information at the National Association of Boards of Pharmacy annual meeting on California's electronic pedigree requirements in both a poster session and a full presentation to the full assembly.</i></p> <p><i>June 2007: Board convenes sixth Workgroup on E-pedigree Meeting, with the largest attendance of any prior meeting. Presentations were made by EPCglobal, Pfizer, Walgreens and PhRMA. Hospital pharmacies were specifically invited to attend this meeting.</i></p> <p><i>Dec. 2007: Enforcement Committee Meeting solely dedicated to workgroup on E-Pedigree (an eight-hour meeting). Largest meeting to date involving over 400 individuals representing all members in the pharmaceutical supply chain. Board encourages discussion of grandfathering and inference, and seeks information via a template. Industry seeks delay. Many request board to specify technology. Board releases template for readiness assessment.</i></p> <p><i>Jan. 2008: Board reviews requests for delay until 2011 from members of the pharmaceutical supply chain.</i></p>

2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products.
Sept. 2006: Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.
Oct. 2006: Board adds Consumer friendly materials regarding sales of these drugs to its Website.
July 2007: Board hears presentations on EPCglobal standards.
Sept. 2007: Enforcement Meeting has large audience (200 people). Presentations by PhRMA, GSK, Bracco, CPhA, EPCglobal, Walgreens, Rite Aid, CVS, rfxcel, and HDMA. Federal legislation enacted for the FDA supports California requirements. Major presentations made on California's standards to LogiPharma (Philadelphia) and HDMA Subcommittee of board meets with EPCglobal representatives on standards.
Oct. 2007: Major presentations at EPCglobal Conference in Chicago. At Board Meeting, presentations made by IBM/Amerisource Bergen, Alien Technology and EPCglobal on readiness of technology.
3. Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances.
Sept. 2006: DEA releases proposed rule to allow prescribers to issue 90 days' worth of Schedule II prescriptions at one time.
Oct. 2006: Board considers proposed rule.
Nov. 2006: Board submits letter supporting change in DEA policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.
2nd Qtr 07/08: DEA agrees to allow a 90-day supply of Schedule II drugs to be prescribed at one time in serial prescriptions.
4. Evaluate establishment of an ethics course as an enforcement option.
June 2007 Subcommittee meets with ethicist trainer for Dental Board.
Aug. 2007: Subcommittee meets with Medical Boards Ethics course provider (Institute for Medical Quality).
Oct. 2007: Institute for Medical Quality provides information to board about program; recommendation of committee is to move forward with the specialized program. Board approves development of program at board meeting.
Jan. 2008: Staff compile resource materials and begin steps to develop framework for program. Legislative proposal developed for board approved.
5. Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.
May 2007: Board staff provides presentation at National Association of Boards of Pharmacy annual meeting on California's pedigree requirements.
June 2007: Board works with Center for Medicare and Medicaid Services on security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.
Nov. 2007: Staff meets with FDA officials to discuss California's e-Pedigree requirements and new federal law for FDA's action involving pharmaceutical chain security.
6. Provide information about legal requirements involving e-prescribing to support the Governor's Health Care Initiative and its promotion of e-prescribing.
Sept. 2007: Provided comments on proposed statutory requirements.
Dec. 2007: Sought DCA's support for involvement in e-prescribing by the Administration.

	<p>7. Implement in California the Center for Medicare and Medicaid Service requirements for security prescription forms that will be required in only four months for all written Medicaid and Medicare prescriptions.</p> <p>June - Oct. 007: Board works with the Department of Health Care Services to implement security forms until subsequent federal legislation delays implementation until April 2008.</p> <p>Dec. 2007: Meeting with Department of Health Care Services on issues involving security forms for MediCal prescriptions.</p> <p>8. Liaison with other state and federal agencies to achieve consumer protection.</p> <p>1st Qtr 07/08: Bimonthly meetings initiated with Department of Health Care Services audit staff to investigate pharmacies and pharmacists involved in MediCal fraud and drug diversion. Several joint investigations underway with state and federal agencies.</p> <p>2nd Qtr 07/08: Bimonthly meeting with the DHCS continue. Board Inspectors attend 3-day-training with federal and state regulations on items involving fraud provided by the Office of Inspector General of the Department of Health and Human Services. Joint investigations with other state and federal agencies continue that involve the board's jurisdiction.</p>
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